STORAGE OF DONATED KIDNEYS: Data Extraction

Moustafellos et al. (2008)

DESIGN

Study design:
Retrospective record review

Country (countries):
UK

Number of centres:
1

Recruitment dates:
2004-2006

Length of follow-up:
-

Source of funding:
not reported

ARM(S)

ARM 1:
LifePort
Intervention: Machine perfusion
Number enrolled: 18

ARM 2:
University of Wisconsin cold storage solution
Intervention: Cold storage
Number enrolled: 18

PARTICIPANTS

Number enrolled:
36

Attrition / dropout:
-

Inclusion criteria:
Class III or IV DCD donors

Exclusion criteria:
-

ANALYSIS

Primary outcome measure:
Immediate renal function

Secondary outcome measure(s):
Delayed graft function
Length of hospitalisation
Mean creatinine levels at discharge

Method of assessing outcomes:
DGF not defined

CHARACTERISTICS OF PARTICIPANTS

	LifePort				University of Wisconsin cold storage solution				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Age years -recipient	18	-	36.3[a]	0	18	-	54.5[b]	0	-18.2	0	<0.001[c]
Gender (n male)	18	13	-	-	18	10	-	-	-	-	-
HLA mismatches	18	-	2.4	0	18	-	2.1	0	-	-	-

Notes
[a] *range (20-66)*
[b] *range (36 -69)*
[c] *student's t-test (calculated by reviewer)*

RESULTS

	LifePort				University of Wisconsin cold storage solution				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Cold ischemia (mins)	18	-	909	-	18	-	999	-	-90	0	<0.001[b]
Creatinine (umol/L at discharge)	18	-	385.6	-	18	-	503.1	-	-118	0	<0.001[b]
Death due to infection	18	1	-	-	18	0	-	-	3	4.96	0.468[a]
DGF RR	18	5	-	-	18	16	-	-	0.313	1.48	<0.001[a]
Hospitalisation (days)	18	-	8.1	1.8	18	-	14.1	3.1	-6	0.845	<0.001[b]
IRF	18	13	-	-	18	2	-	-	6.5	1.98	<0.001[a]
Rejection of graft	18	0	-	-	18	0	-	-	1	7.2	1.000[a]
LOSS OF GRAFT											
Post-operative period	18	0	-	-	18	0	-	-	1	7.2	1.000[a]
Surgical technique/preparation	18	-	-	-	18	0	-	-	1	7.2	1.000[a]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *student's t-test (calculated by reviewer)*

ASSESSMENT OF STUDY QUALITY

1. **Were inclusion criteria appropriate?**
   YES
2. **Was the method of selection reported?**
   NO
3. **Was the method of allocation reported?**
   NO
4. **were I and C groups treated the same?**
   NO - the groups received different induction therapies
5. **Were I and C groups similar at baseline?**
   NO - The cold storage group were older by an average of 18 years
6. **Were assessors blinded to allocation?**
   NOT REPORTED

STORAGE OF DONATED KIDNEYS: Data Extraction

Moustafellos et al. (2007)

7. **Was the follow up time adequate?**
   NOT REPORTED
8. **How were missing data accounted for?**
   NOT REPORTED
9. **Were confounders accounted for in analysis?**
   NOT REPORTED
10. **Was inter centre variability reported?**
    NA
11. **Are the results generalisable?**
    NO - method of allocation to group is unknown (not randomised), the groups have baseline differences and the numbers are small (36)
12. **Are conflict of interests declared?**
    NO

STORAGE OF DONATED KIDNEYS: Data Extraction

Plata-Munoz et al. (2008)

DESIGN

Study design:
cohort study

Country (countries):
UK

Number of centres:
1

Recruitment dates:
March 2002 - December 2005

Length of follow-up:
1 year

Source of funding:
-

ARM(S)

ARM 1:
LifePort
Intervention: Machine perfusion
Number enrolled: 30

ARM 2:
Marshall cold storage solution
Intervention: Cold storage
Number enrolled: 30

PARTICIPANTS

Number enrolled:
60

Attrition / dropout:
-

Inclusion criteria:
DCD Maastricht category III
<65 years

Exclusion criteria:
Donors:
Diabetes
Primary renal disease
Systemic sepsis
Malignancy

ANALYSIS

Primary outcome measure:
not specified

Secondary outcome measure(s):
Primary non function PNF
Delayed graft function DGF
Immediate graft function IGF
Acute rejection
1 year graft function
1 year graft survival
I year patient survival
Length of hospitalisation
Warm ischaemic time
Cold ischaemic time
Serum creatinine
HLA matching

Method of assessing outcomes:
DGF: the need for dialysis during the first week after transplantation, excluding those episodes of dialysis secondary to fluid overload or hyperkalaemia during the first 24 hours post-transplant.

CHARACTERISTICS OF PARTICIPANTS

	LifePort				Marshall cold storage solution				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Implantation time (mins)	30	-	55[i]	-	30	-	40[h]	-	15	-	-
DONOR											
Age	30	-	41.6	2.9	30	-	40.3	2.6	1.3	0.711	0.073[o]
Cerebrovascular disease	30	11	-	-	30	12	-	-	0.917	1.39	0.791[a]
Creatinine clearance (umol/L)	30	-	95[j]	-	30	-	103[k]	-	-	-	-
Gender (n male)	30	17	-	-	30	18	-	-	0.944	1.24	0.793[a]
Hypertension	30	3	-	-	30	5	-	-	0.6	1.98	0.448[a]
HLA MISMATCHES											
0	30	1	-	-	30	1	-	-	1	4.02	1.000[a]
1-2	30	8	-	-	30	14	-	-	0.571	1.43	0.108[a]
3-4	30	18	-	-	30	15	-	-	1.2	1.27	0.436[a]
5-6	30	1	-	-	30	0	-	-	3	5.02	0.472[a]
INDUCTION THERAPY											
Alemtuzimab	30	15	-	-	30	1	-	-	15	2.72	<0.001[a]
Anti-thymocite Globuline	30	2	-	-	30	28	-	-	0.0714	1.98	<0.001[a]
Basiliximab	30	13	-	-	30	1	-	-	13	2.73	<0.001[a]
MAINTENANCE THERAPY											
Prednisolone	30	15	-	-	30	30	-	-	0.508	1.2	<0.001[a]
Tacrolimus/Sir + MMF	30	30	-	-	30	30[l]	-	-	1	1.03	1.000[a]
PRE-IMPLANTATION DATA											
Cold ischaemic time > 24 hrs	30	7	-	-	30	5	-	-	1.4	1.69	0.519[a]
Cold ischaemic time 14-18 hrs	30	9	-	-	30	8	-	-	1.13	1.51	0.774[a]
Cold ischaemic time 18-24 hrs	30	10	-	-	30	12	-	-	-	-	-
Cold ischaemic time (mins)	30	-	1115[e]	0	30	-	1076[d]	0	-	-	-
Cold ischaemic time <12 hrs	30	0	-	-	30	1	-	-	0.333	5.02	0.472[a]
Cold ischaemic time <14 hrs	30	4	-	-	30	4	-	-	1	1.93	1.000[a]
Warm ischaemic time (mins)	30	-	18[b]	-	30	-	18.5[c]	-	-0.5	-	-
RECIPIENT											
Age	30	-	47[m]	-	30	-	54[n]	-	-7	-	-
Days on waiting list	30	-	493[g]	-	30	-	410[f]	-	83	-	-
First transplant	30	25	-	-	30	29	-	-	0.862	1.09	0.085[a]
Gender (n male)	30	20	-	-	30	19	-	-	1.05	1.21	0.787[a]
Highly sensitized PRA (>85%)	30	2	-	-	30	1	-	-	2	3.31	0.554[a]
Pre-transplant antibodies	30	16	-	-	30	10	-	-	1.6	1.36	0.118[a]

Notes

[a] *chi-square test (calculated by reviewer)*

Plata-Munoz et al. (2008)

[b] *Median, inter-quartile range (13-30)*
[c] *Median, inter-quartile range (15-23)*
[d] *Median, inter-quartile range (876-1320)*
[e] *Median, inter-quartile range (918-1363)*
[f] *Median, range (176-683)*
[g] *Median, range (291-1220)*
[h] *Median, range (32-60)*
[i] *Median, range (43-630*
[j] *Median, range (65-106)*
[k] *Median, range (69-120)*
[l] *MMF Mycophenolate of Mophetil*
[m] *range 20 - 69 years*
[n] *range 34 - 76 years*
[o] *student's t-test (calculated by reviewer)*

RESULTS

	LifePort				Marshall cold storage solution				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Acute rejection	30	4	-	-	30	2	-	-	2	2.29	0.389[a]
Creatinine (umol/L at 1 month)	30	-	199	20	30	-	282	33	-83	7.05	<0.001[b]
Creatinine day 7 (umol/L)	30	-	259	27	30	-	461	33	-202	7.78	<0.001[b]
GF 1 year	30	-	154	9	30	-	193	25	-39	4.85	<0.001[b]
GF 6 months	30	-	163	10	30	-	201	21	-38	4.25	<0.001[b]
Graft loss	30	1	-	-	30	1	-	-	1	4.02	1.000[a]
Graft survival (1 year)	30	30	-	-	30	28	-	-	1.07	1.06	0.237[a]
Graft survival (2 year)	30	29	-	-	30	27	-	-	1.07	1.07	0.301[a]
Hospitalisation (days)	30	-	10	-	30	-	14	-	-4	-	-
IRF	30	17	-	-	30	4	-	-	4.25	1.64	<0.001[a]
Patient loss	30	1	-	-	30	1	-	-	1	4.02	1.000[a]
Patient survival (1 year)	30	30	-	-	30	28	-	-	1.07	1.06	0.237[a]
Patient survival (2 year)	30	29	-	-	30	27	-	-	1.07	1.07	0.301[a]
PNF	30	0	-	-	30	0	-	-	-	-	-
Serum Creatinine mmol/dl (1 year)	30	-	112	14.9	30	-	184	23	-72	5	<0.001[b]
DGF											
DGF total	30	16	-	-	30	25	-	-	0.64	1.21	0.012[a]
First 15 transplants	30	8	-	-	30	14	-	-	0.571	1.43	0.108[a]
Second 15 transplants	30	8	-	-	30	12	-	-	0.667	1.46	0.273[a]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *student's t-test (calculated by reviewer)*

ASSESSMENT OF STUDY QUALITY

1. **Were inclusion criteria appropriate?**
   YES
2. **Was the study prospective**
   YES
3. **Was method of selection reported?**
   NO
4. **Was the method of allocation reported?**
   YES
5. **Were I and C groups treated the same other than the intervention?**
   UNCLEAR
6. **were I and C groups similar at baseline?**
   NO - The machine preservation recipients were younger
7. **Were I and C groups assessed the same?**
   UNCLEAR
8. **Was there a power calculation?**
   NO - Not applicable
9. **Were assessors blind to allocation?**
   UNCLEAR
10. **Was follow up time adequate to show outcomes to change?**
    YES

Plata-Munoz et al. (2008)

11. **Was analysis by ITT?**
    UNCLEAR
12. **Was attrition reported?**
    NO
13. **Were missing data accounted for?**
    UNCLEAR
14. **Were confounders accounted for in analysis?**
    UNCLEAR
15. **Was inter centre variability reported?**
    NA
16. **Are the results generalisable?**
    PARTIALLY - To DCD III donors
17. **Was ethical approval given?**
    NOT REPORTED
18. **Were conflict of interest declared?**
    NO

STORAGE OF DONATED KIDNEYS: Data Extraction

Guarrera et al. (2007)

DESIGN

Study design:
Retrospective record review

Country (countries):
USA

Number of centres:
1

Recruitment dates:
Dec 2001 - Sep 2006

Length of follow-up:
1 year

Source of funding:
-

ARM(S)

ARM 1:
RM3
Intervention: Machine perfusion
Number enrolled: 280

ARM 2:
LifePort
Intervention: Machine perfusion
Number enrolled: 305

PARTICIPANTS

Number enrolled:
774

Attrition / dropout:
190 kidneys were discarded after storage (RM3 = 98 (26%), LifePort = 91 (23%), ns)

Inclusion criteria:
ECD:
Donor age > 60 years
Donor age > 50 -59 + hypertension
Diabetes > 5 years
GFR < 70 ml/min or an admit serum creatinine of >1.5 mg/dl
Any DCD
a serum creatinine level that doubles from admit to final
Other: prolonged cold ischaemia, disseminated intravascular coagulopathy

Exclusion criteria:
-

ANALYSIS

Primary outcome measure:
DGF

Secondary outcome measure(s):
Graft function, 6 months, 1 year
Graft survival
Primary non-function
Recipient 1 year SCr (mg/dL)

Method of assessing outcomes:
Abstract and poster only

CHARACTERISTICS OF PARTICIPANTS

	RM3				LifePort				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
DONOR											
Age years	378	-	52[g]	-	396	-	51[d]	-	1	-	[h]
DCD	378	75	-	-	396	96	-	-	0.851	1.14	0.213[a]
Hx of Hypertension	378	185	-	-	396	198	-	-	0.979	1.08	0.769[a]
ETHNIC GROUP - DONOR											
African American	378	91	-	-	396	103	-	-	0.962	1.12	0.744[a]
Caucasian	378	249	-	-	396	253	-	-	1.07	1.03	0.038[a]
Hispanic	378	34	-	-	396	32	-	-	1.16	1.26	0.528[a]
Other	378	4	-	-	396	8	-	-	0.545	1.83	0.309[a]
RECIPIENT											
Admit creatinine	378	-	1[c]	0.3	396	-	1.1[b]	0.5	-0.1	0.0338	0.003[h]
Age years	378	-	52.4[f]	-	396	-	50.5[e]	-	1.9	-	[h]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *range 0.2 - 15.3*
[c] *range 0.2 - 2.3*
[d] *range 11 -79 years*
[e] *range 11-79*
[f] *range 2-80*
[g] *range 2-80 years*
[h] *student's t-test (calculated by reviewer)*

RESULTS

	RM3				LifePort				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Cold ischemia (hours)	378	-	23[m]	-	396	-	24.3[l]	-	-1.3	-	[n]
Creatinine 1 year (mg/dL)	289	-	1.91	0.9	305	-	1.83	1.1	0.08	0.0823	0.331[n]
DCD	280	-	-	-	305	-	-	-	0.851	1.14	0.213[a]
DGF	289	90	-	-	396	162	-	-	0.761	1.11	0.009[a]
Discard rate	378	98	-	-	396	91	-	-	1.13	1.13	0.340[a]
Flow of solution (CC/min)	280	-	129[k]	-	305	-	145[j]	-	-16	-	[n]
PNF	378	11	-	-	396	8	-	-	1.44	1.58	0.424[a]
Renal resistance (map/flow)	280	-	0.32[b]	-	305	-	0.28[d]	-	0.04	0	<0.001[n]
Total cold ischaemia (hours)	378	-	23	-	398	-	24.3	-	-1.3	0	<0.001[n]
Transplanted > 60 yrs	378	92	-	-	396	85	-	-	1.13	1.14	0.341[a]

STORAGE OF DONATED KIDNEYS: Data Extraction

Guarrera et al. (2007)

	RM3				LifePort				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
GRAFT FUNCTION											
1 year	378	347	-	-	396	339	-	-	1.07	1.03	0.007[a]
Final creatinine	378	-	1.46[c]	0.8	396	-	1.5[e]	0.9	-0.04	0.0611	0.513[n]
Glomerular filtration rate	378	-	91.2[i]	-	396	-	95[h]	-	-3.8	-	[n]
GRAFT SURVIVAL											
1 year	378	366[f]	-	-	396	367[g]	-	-	1.04	1.02	0.010[a]
PATIENT SURVIVAL											
1 year	378	366	-	-	396	367	-	-	1.04	1.02	0.010[a]

Notes

[a] *chi-square test (calculated by reviewer)*
[b] *range 0.05-9.99*
[c] *range 0.2 - 4.6*
[d] *range 0.28-1.06*
[e] *range 0.4 - 10.8*
[f] *range 0.7-10.6*
[g] *range 0.8-11.3*
[h] *range 17-198*
[i] *range 23.8-182*
[j] *range 39-199*
[k] *range 5-218*
[l] *range 8-58*
[m] *range 9-47.5*
[n] *student's t-test (calculated by reviewer)*

ASSESSMENT OF STUDY QUALITY

1. **Were inclusion criteria appropriate?**
   YES
2. **Was the method of selection reported?**
   YES
3. **Was the method of allocation reported?**
   YES
4. **were I and C groups treated the same?**
   UNCLEAR
5. **Were I and C groups similar at baseline?**
   YES
6. **Were assessors blinded to allocation?**
   NOT REPORTED
7. **Was the follow up time adequate?**
   NOT REPORTED
8. **How were missing data accounted for?**
   NOT REPORTED
9. **Were confounders accounted for in analysis?**
   NOT REPORTED
10. **Was inter centre variability reported?**
    NA
11. **Are the results generalisable?**
    PARTIALLY - As the study was not randomised and use of machines sequential other variables may have influenced the outcomes
12. **Are conflict of interests declared?**
    NO

STORAGE OF DONATED KIDNEYS: Data Extraction

Kazimi et al. (2007)

DESIGN

Study design:
Retrospective record review

Country (countries):
USA

Number of centres:
1

Recruitment dates:
Feb 2005 - Nov 2006

Length of follow-up:
not reported

Source of funding:
not reported

ARM(S)

ARM 1:
Lifeport
Intervention: Machine perfusion
Number enrolled: 52

ARM 2:
RM3
Intervention: Machine perfusion
Number enrolled: 37

PARTICIPANTS

Number enrolled:
89

Attrition / dropout:
-

Inclusion criteria:
Renal allographs brought in or handled by the perfusion laboratory that were either:
kidney
kidney/liver
kidney/pancreas

Exclusion criteria:
-

ANALYSIS

Primary outcome measure:
Graft survival- GS

Secondary outcome measure(s):
Post-transplant dialysis
length of hospital stay
rate of improvement in creatinine levels

Method of assessing outcomes:
Abstract and poster only

Outcome data were from the transplant registry database. Analysis used SPSS. Chi-square and Mann-Whitney tests were used for group comparisons, $p<0.05$ was considered significant.

The LifePort machine has been used most recently, therefore there are issues about confounding variables and bias

CHARACTERISTICS OF PARTICIPANTS

	Lifeport				RM3				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Age years -recipient	52	-	48	-	37	-	46	-	2	-	[b]
DONOR -age	52	-	30	-	37	-	32	-	-2	-	[b]
DONOR- terminal creatinine	52	-	1	-	37	-	1.1	-	-0.1	-	[b]
Pre-op Creatinine - recipient	52	-	5.4	-	37	-	8.2	-	-2.8	-	[b]
Sex (n male)-recipient	52	42	-	-	37	20	-	-	1.49	1.18	0.007[a]
DONOR TYPE											
BSD	52	51	-	-	37	36	-	-	1.01	1.03	0.807[a]
DCD	52	1	-	-	37	1	-	-	0.712	4.05	0.807[a]
ETHNIC GROUP - RECIPIENT											
black	52	8	-	-	37	11	-	-	0.517	1.51	0.104[a]
Other	52	6	-	-	37	2	-	-	2.13	2.2	0.319[a]
White	52	38	-	-	37	24	-	-	1.13	1.16	0.406[a]
TRANSPLANT TYPE											
kidney or kidney/pancreas (import)	52	4	-	-	37	6	-	-	0.474	1.84	0.210[a]
kidney or kidney/pancreas (local)	52	29	-	-	37	27	-	-	-	-	-
kidney/liver (local)	52	19	-	-	37	4	-	-	3.38	1.66	0.006[a]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *student's t-test (calculated by reviewer)*

RESULTS

	Lifeport				RM3				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
% change in creatinine at 48 hrs post Tx	52	-	28	-	37	-	35	-	-7	-	[b]
% change in creatinine at hospital discharge	52	-	65	-	37	-	71	-	-6	-	[b]
Hospitalisation (days)	52	-	15	-	37	-	9	-	6	-	[b]
post transplant dialysis	52	2	-	-	37	2	-	-	0.712	2.66	0.726[a]
GRAFT SURVIVAL											
30 days	52	49	-	-	37	36	-	-	0.968	1.04	0.491[a]
90 days	41	37	-	-	36	35	-	-	0.928	1.06	0.215[a]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *student's t-test (calculated by reviewer)*

STORAGE OF DONATED KIDNEYS: Data Extraction

Kazimi et al. (2007)

ASSESSMENT OF STUDY QUALITY

1. **Were inclusion criteria appropriate?**
   UNCLEAR - This was a poster presentation, therefore information is limited
2. **Was the method of selection reported?**
   YES
3. **Was the method of allocation reported?**
   NO
4. **were I and C groups treated the same?**
   UNCLEAR
5. **Were I and C groups similar at baseline?**
   NO - There were more men in the RM3 group ($p<0.01$) and more participants in the LifePort group ($p<0.02$)
6. **Were assessors blinded to allocation?**
   NOT REPORTED
7. **Was the follow up time adequate?**
   NOT REPORTED
8. **How were missing data accounted for?**
   NOT REPORTED
9. **Were confounders accounted for in analysis?**
   NOT REPORTED
10. **Was inter centre variability reported?**
    YES - in baseline characteristics but not in the results
11. **Are the results generalisable?**
    NO - this was a non randomised study with the RM3 being used historically before the LifePort machine, other confounding variables may have biased the resul
12. **Are conflict of interests declared?**
    NO

STORAGE OF DONATED KIDNEYS: Data Extraction

Opelz & Dohler (2007)

DESIGN

Study design:
Retrospective record review

Country (countries):
26 countries in Europe, North America and Australia

Number of centres:
195

Recruitment dates:
1990 - 2005

Length of follow-up:
3,6,12 months and then yearly

Source of funding:
-

ARM(S)

ARM 1:
University of Wisconsin cold storage solution
Intervention: Cold storage
Number enrolled: 53560

ARM 2:
Marshall cold storage solution
Intervention: Cold storage
Number enrolled: 5047

PARTICIPANTS

Number enrolled:
58607

Attrition / dropout:
-

Inclusion criteria:
kidneys transplanted from deceased donors

Exclusion criteria:
-

ANALYSIS

Primary outcome measure:
Graft survival

Secondary outcome measure(s):
Death censored functional survival

Method of assessing outcomes:
Analysis was limited to transplants between 1990 -2004. DGF data was not collected due to lack of standardisation. Graft survival rates and death censored functional graft suvuval rates were analysed with Kaplan Meier methods. Logistic regression and Cox regression analysis were used on covariables.

These data are a subset taken from the Collaborative Transplant Study www.ctstransplant.org

CHARACTERISTICS OF PARTICIPANTS

RESULTS

	University of Wisconsin cold storage solution				Marshall cold storage solution				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
GRAFT SURVIVAL 3 YEARS FOLLOW UP											
>36 hours of cold ischaemia	2486	1855	-	-	303	220	-	-	1.03	1.04	0.449[a]
0-18 hours of cold ischaemia	24258	19746	-	-	2225	1782	-	-	1.02	1.01	0.129[a]
19-24 hours of cold ischaemia	16147	12756	-	-	1636	1260	-	-	1.03	1.01	0.062[a]
25-36 hours of cold ischaemia	11158	8636	-	-	944	709	-	-	1.03	1.02	0.107[a]

Notes

[a] *chi-square test (calculated by reviewer)*

ASSESSMENT OF STUDY QUALITY

1. **Were inclusion criteria appropriate?**
   YES
2. **Was the method of selection reported?**
   YES
3. **Was the method of allocation reported?**
   NO
4. **were I and C groups treated the same?**
   UNCLEAR
5. **Were I and C groups similar at baseline?**
   UNCLEAR
6. **Were assessors blinded to allocation?**
   NOT REPORTED
7. **Was the follow up time adequate?**
   YES
8. **How were missing data accounted for?**
   NOT REPORTED
9. **Were confounders accounted for in analysis?**
   NOT REPORTED
10. **Was inter centre variability reported?**
    NO
11. **Are the results generalisable?**
    YES - Due to very large sample size

Opelz & Dohler (2007)

12. Are conflict of interests declared?

NO

STORAGE OF DONATED KIDNEYS: Data Extraction

Montalti et al. (2005)

DESIGN

Study design:
Prospective multi-centre RCT

Country (countries):
Italy

Number of centres:
2 Bologna and Palma

Recruitment dates:
Nov 1998 - Sept 2000

Length of follow-up:
5 years

Source of funding:
Not reported

ARM(S)

ARM 1:

University of Wisconsin cold storage solution

Intervention: Cold storage

Number enrolled: 25

As 6 kidneys from the 30 randomised to this group were rejected it is assumed that one of the kidneys randomised to Celsior solution was changed to UW.

ARM 2:

Celsior cold storage solution

Intervention: Cold storage

Number enrolled: 25

PARTICIPANTS

Number enrolled:
60

Attrition / dropout:
10 kidneys were rejected following histologic examination (UW =6, Celsior =4)

Inclusion criteria:
Deceased multiple organ donors > 60 years

Exclusion criteria:
-

ANALYSIS

Primary outcome measure:
Delayed graft function DGF

Secondary outcome measure(s):
urinary output
serum creatinine

Method of assessing outcomes:
Graft survival was calculated using Kaplan Meier analysis

DGF - the absence of life-sustaining renal function requriing one or more dialysis session withing the first days after transplantation

CHARACTERISTICS OF PARTICIPANTS

	University of Wisconsin cold storage solution				Celsior cold storage solution				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
DONOR											
Age years	25	-	66.2	4.1	25	-	66.4	4.2	-0.2	1.17	0.865[a]
Terminal creatinine	25	-	1.2	0.9	25	-	1	0.3	0.2	0.19	0.297[a]
Urinary output per hour (mL)	25	-	248	130	25	-	236	60	12	28.6	0.677[a]
RECIPIENT											
Age years	25	-	54.5	7.4	25	-	55.2	8.3	-0.7	2.22	0.754[a]

Notes

[a] *student's t-test (calculated by reviewer)*

RESULTS

	University of Wisconsin cold storage solution				Celsior cold storage solution				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
A mismatches	25	-	0.9	-	25	-	0.9	-	0	-	[b]
Acute rejection	25	2	-	-	25	2	-	-	1	2.61	1.000[a]
B mismatches	25	-	1.1	-	25	-	0.9	-	0.2	-	[b]
Cold ischaemic time (hours)	25	-	19	6.5	25	-	18	4.5	1	1.58	0.530[b]
DGF	25	13	-	-	25	12	-	-	1.08	1.33	0.777[a]
DR mismatches	25	-	1.2	-	25	-	0.8	-	0.4	-	[b]
Panel reactive anitbodies	25	-	18.2	22.3	25	-	13.3	18.3	4.9	5.77	0.400[b]
Post -operative dialysis	25	-	3.1	4.9	25	-	2.2	3.8	-	-	-
Warm ischaemic time (mins)	25	-	46.9	17.9	25	-	42.4	11	4.5	4.2	0.290[b]
GRAFT SURVIVAL											
1 year	25	24	-	-	25	23	-	-	1.04	1.07	0.552[a]
5 years	25	22	-	-	25	20	-	-	1.1	1.13	0.440[a]

Notes

[a] *chi-square test (calculated by reviewer)*

[b] *student's t-test (calculated by reviewer)*

ASSESSMENT OF STUDY QUALITY

1. **Are the study aims clearly described and focused?**
   YES
2. **Is study design appropriate to answer these aims?**
   YES
3. **Are there explicit inclusion and exclusion criteria for the study?**
   PARTIAL
4. **Are methods of randomisation adequate?**
   NOT REPORTED

STORAGE OF DONATED KIDNEYS: Data Extraction

Montalti et al. (2005)

5. **Was there concealed randomised allocation?**
   UNCLEAR
6. **Are sample characteristics adequately described?**
   YES - Extended criteria donors
7. **Are there significant differences between the cohorts?**
   NO
8. **Was the follow up time adequate for outcomes to change?**
   YES
9. **Do analyses attempt to control for confounders?**
   CAN'T TELL
10. **Is there a power calculation?**
    CAN'T TELL
11. **Is the sample size sufficient?**
    NOT ANALYSED
12. **Is primary outcome measure objective?**
    OBJECTIVE
13. **Are secondary outcome measures objective?**
    OBJECTIVE
14. **Were outcome assessors blind to exposure status?**
    CAN'T TELL
15. **Are drop-out rates similar between intervention and controls?**
    CAN'T TELL
16. **was analysis by ITT**
    NOT REPORTED
17. **Inter centre variability reported?**
    NO
18. **Are the results generalisable?**
    PARTIALLY - The donors were over 60 years old, this may affect the quality of their kidneys
19. **Was ethical approval given?**
    NOT REPORTED
20. **Were all groups treated similarly?**
    CAN'T TELL
21. **Were all participants accounted for?**
    YES

STORAGE OF DONATED KIDNEYS: Data Extraction

Marcen et al. (2005)

DESIGN

Study design:
Retrospective record review

Country (countries):
Spain

Number of centres:
1

Recruitment dates:
Jan 1997 - Oct 2001

Length of follow-up:
12 months

Source of funding:
-

ARM(S)

ARM 1:
University of Wisconsin cold storage solution
Intervention: Cold storage
Number enrolled: 138

ARM 2:
Celsior cold storage solution
Intervention: Cold storage
Number enrolled: 39

PARTICIPANTS

Number enrolled:
177

Attrition / dropout:
-

Inclusion criteria:
Deceased donors
Brain death diagnosed BSD

Exclusion criteria:
-

ANALYSIS

Primary outcome measure:
Delayed graft function DGF

Secondary outcome measure(s):
Primary non-fucntion PNF
Serum creatinine
Graft survival GS

Method of assessing outcomes:
Chi-squared test to compare categorical data, with t test and Mann-Whitney tests as indicated. Graft survival was clculated using the Kaplan -Meiter method.

CHARACTERISTICS OF PARTICIPANTS

	University of Wisconsin cold storage solution				Celsior cold storage solution				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Age- donor (years)	138	-	42.3	16.9	39	-	38.1	12.5	4.2	2.46	0.090[b]
Age years -recipient	138	-	49.5	14.4	39	-	43.3	13	6.2	2.42	0.011[b]
DONOR- terminal creatinine	138	-	1.1	0.6	39	-	0.9	0.8	0.2	0.138	0.149[b]
RECIPIENT body mass index (kg/m2)	138	-	24.4	5.5	39	-	24	5.8	0.4	1.04	0.701[b]
RECIPIENT Sex (n male)	138	85	-	-	39	23	-	-	1.04	1.16	0.767[a]
RECIPIENT time on dialysis prior to Tx (years)	138	-	2.5	2.7	39	-	2	1.6	0.5	0.344	0.148[b]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *student's t-test (calculated by reviewer)*

Characteristic	**N**	**k**	**Mean**	**SD**
Age years -recipient	177	-	48.1	13.5
RECIPIENT Sex (n male)	177	107	-	-
RECIPIENT time on dialysis prior to Tx (years)	17	-	2.4	2.5

RESULTS

	University of Wisconsin cold storage solution				Celsior cold storage solution				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Acute rejection	138	23	-	-	39	2	-	-	-	-	-
Acute rejection RR	138	-	-	-	39	-	-	-	3.25	2.04	0.068[a]
Cold ischemia (hours)	138	-	17.5	4.3	39	-	16.9	3.7	-	-	-
Cold ischemia (hours) RR	138	-	-	-	39	-	-	-	0.6	0.696	0.390[b]
Creatinine (umol/L at 1 month)	138	-	1.9	0.9	39	-	1.5	0.5	-	-	-
Creatinine (umol/L at 1 month) RR	138	-	-	-	39	-	-	-	0.4	0.111	<0.001[b]
Creatinine (umol/L at 12 months	-	-	-	-	39	-	1.35	0.4	-	-	-
Creatinine (umol/L at 12 months)	138	-	1.63	0.5	-	-	-	-	-	-	-
Creatinine (umol/L at 12 months) RR	138	-	-	-	39	-	-	-	0.28	0.0769	<0.001[b]
DGF RR	-	-	-	-	39	9	-	-	-	-	-
DGF RR	138	54	-	-	39	-	-	-	1.7	1.36	0.064[a]
Graft survival (12 months)	138	121	-	-	39	38	-	-	-	-	-
Graft survival (12 months) RR	138	-	-	-	39	-	-	-	0.9	1.04	0.075[a]
PNF	138	8	-	-	39	1	-	-	-	-	-
PNF RR	138	-	-	-	39	-	-	-	2.26	2.84	0.417[a]
Rejection of graft	138	23	-	-	39	2	-	-	-	-	-
Rejection of graft RR	138	-	-	-	39	-	-	-	3.25	2.04	0.068[a]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *student's t-test (calculated by reviewer)*

STORAGE OF DONATED KIDNEYS: Data Extraction

Marcen et al. (2005)

ASSESSMENT OF STUDY QUALITY

1. **Were inclusion criteria appropriate?**
   YES
2. **Was the method of selection reported?**
   YES
3. **Was the method of allocation reported?**
   NO
4. **were I and C groups treated the same?**
   UNCLEAR
5. **Were I and C groups similar at baseline?**
   NO - recipients in the UW group were older, there were many more people in the UW group
6. **Were assessors blinded to allocation?**
   NOT REPORTED
7. **Was the follow up time adequate?**
   YES
8. **How were missing data accounted for?**
   NOT REPORTED
9. **Were confounders accounted for in analysis?**
   NOT REPORTED
10. **Was inter centre variability reported?**
    NA
11. **Are the results generalisable?**
    PARTIALLY - This was not a RCT and so biases may have been present and the numbers in the two groups are very unbalanced
12. **Are conflict of interests declared?**
    NO

STORAGE OF DONATED KIDNEYS: Data Extraction

Pedotti et al. (2004)

DESIGN

Study design:
Prospective multi-centre RCT

Country (countries):
Italy

Number of centres:
16

Recruitment dates:
March 2000- Dec 2001

Length of follow-up:
12 months

Source of funding:
-

ARM(S)

ARM 1:
University of Wisconsin cold storage solution
Intervention: Cold storage
Number enrolled: 269

ARM 2:
Celsior cold storage solution
Intervention: Cold storage
Number enrolled: 172

PARTICIPANTS

Number enrolled:
441

Attrition / dropout:
-

Inclusion criteria:
Deceased multi-organ donors

Exclusion criteria:
non-multi organ donors
from non NITp progamme centres
from centres where included perfusion solutions not available
paediatric patients
regrafts
transplants with missing or incomplete data on follow-up were excluded from analysis

ANALYSIS

Primary outcome measure:
not specified

Secondary outcome measure(s):
DGF
PNF
Patient survival PS
Graft survival GS
Creatinine levels
Urine output

Method of assessing outcomes:
Analysis was conducted by the NITp Reference Centre using SAS v 8.Statistical techniques used were t tests for continuous variables, chi-square forparametric variables. Log transformation was used when necessary. Survival was calculated using the actuarial method. Logistic multivariate analyses were performed to find the role of determinant factors on graft and patient suvival.

CHARACTERISTICS OF PARTICIPANTS

	University of Wisconsin cold storage solution				Celsior cold storage solution				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Age- donor (years)	269	-	45.4	17.2	172	-	46.1	17.2	-0.7	1.68	0.677[b]
Age years -recipient	269	-	46	13.6	172	-	45.3	14	0.7	1.35	0.605[b]
Cold ischaemic time (hours)	269	-	15.3	4.8	172	-	15.1	4.3	0.2	0.439	0.649[b]
HLA MISMATCHES (A, B, DR)											
0-1	269	47	-	-	172	24	-	-	1.25	1.26	0.327[a]
2-4	269	214	-	-	172	138	-	-	0.992	1.05	0.862[a]
5-6	269	8	-	-	172	10	-	-	0.512	1.59	0.142[a]
PANEL REACTIVE ANTIBODIES											
> 30%	269	9	-	-	172	7	-	-	0.822	1.64	0.692[a]
≤ 30%	269	260	-	-	172	165	-	-	1.01	1.02	0.692[a]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *student's t-test (calculated by reviewer)*

RESULTS

	University of Wisconsin cold storage solution				Celsior cold storage solution				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Acute tubular necrosis	269	28	-	-	172	19	-	-	0.942	1.32	0.832[a]
DGF	269	61	-	-	172	40	-	-	0.975	1.2	0.888[a]
PNF	269	4	-	-	172	4	-	-	0.639	2.01	0.520[a]
COMPLICATIONS											
Infection	269	12	-	-	172	7	-	-	1.1	1.59	0.844[a]
Medical	269	38	-	-	172	31	-	-	0.784	1.25	0.272[a]
none	269	155	-	-	172	85	-	-	-	-	-
Rejection	269	59	-	-	172	31	-	-	1.22	1.22	0.320[a]
Surgical	269	17	-	-	172	20	-	-	0.543	1.37	0.050[a]
CREATININE											
day 1 (µmol/L)[b]	269	-	671.8	102.9	172	-	663	110.4	8.8	10.5	0.402[c]
day 10 (µmol/L)[b]	269	-	246.6	-881.2	172	-	236.7	-549.4	9.9	68.1	0.885[c]
day 15 (µmol/L)[b]	269	-	220.4	-847.7	172	-	200.8	-652.4	19.6	71.7	0.785[c]
day 5 (µmol/L)[b]	269	-	371.3	-463.6	172	-	353.6	-451	17.7	44.5	0.691[c]
GRAFT SURVIVAL											
1 month	269	258	-	-	172	165	-	-	1	1.02	0.992[a]
1 year	269	245	-	-	172	162	-	-	0.967	1.03	0.233[a]

STORAGE OF DONATED KIDNEYS: Data Extraction

Pedotti et al. (2004)

	University of Wisconsin cold storage solution				Celsior cold storage solution				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
PATIENT SURVIVAL											
1 month	269	269	-	-	172	172	-	-	1	1	0.822[a]
1 year	269	263	-	-	172	171	-	-	0.983	1.01	0.177[a]
URINE OUTPUT											
day 1 (mL/24hrs)[b]	269	-	2520	259.4	172	-	2180	-93.68	340	17.4	<0.001[c]
day 10 (mL/24hrs)[b]	269	-	2500	159	172	-	2500	1024	0	78.7	1.000[c]
day 15 (mL/24hrs)[b]	269	-	2500	1305	172	-	2600	381.4	-100	84.7	0.239[c]
day 5 (mL/24hrs)[b]	269	-	2500	150.6	172	-	2600	1512	-100	116	0.388[c]

Notes

[a] *chi-square test (calculated by reviewer)*

[b] *MEDIAN*

[c] *student's t-test (calculated by reviewer)*

ASSESSMENT OF STUDY QUALITY

1. **Are the study aims clearly described and focused?**
   YES
2. **Is study design appropriate to answer these aims?**
   YES
3. **Are there explicit inclusion and exclusion criteria for the study?**
   PARTIAL
4. **Are methods of randomisation adequate?**
   NO - from a list
5. **Was there concealed randomised allocation?**
   NO
6. **Are sample characteristics adequately described?**
   YES
7. **Are there significant differences between the cohorts?**
   NO
8. **Was the follow up time adequate for outcomes to change?**
   YES
9. **Do analyses attempt to control for confounders?**
   CAN'T TELL
10. **Is there a power calculation?**
    CAN'T TELL
11. **Is the sample size sufficient?**
    NOT ANALYSED
12. **Is primary outcome measure objective?**
    OBJECTIVE
13. **Are secondary outcome measures objective?**
    OBJECTIVE
14. **Were outcome assessors blind to exposure status?**
    CAN'T TELL
15. **Are drop-out rates similar between intervention and controls?**
    CAN'T TELL
16. **was analysis by ITT**
    NOT REPORTED
17. **Inter centre variability reported?**
    NO
18. **Are the results generalisable?**
    YES
19. **Was ethical approval given?**
    NOT REPORTED
20. **Were all groups treated similarly?**
    YES
21. **Were all participants accounted for?**
    CAN'T TELL

STORAGE OF DONATED KIDNEYS: Data Extraction

Faenza et al. (2001)

DESIGN

Study design:
Prospective multi-centre RCT

Country (countries):
Italy

Number of centres:
4

Recruitment dates:
Sept 1998 - Sept 2000

Length of follow-up:
2 years

Source of funding:
-

ARM(S)

ARM 1:
University of Wisconsin cold storage solution
Intervention: Cold storage
Number enrolled: 88

ARM 2:
Celsior cold storage solution
Intervention: Cold storage
Number enrolled: 99

PARTICIPANTS

Number enrolled:
187

Attrition / dropout:
13 kidneys were not transplanted (UW = 6, C = 7); these were from marginal donors and rejected on histological grounds by the same pathologist

Inclusion criteria:
Donors and recipients > 15 years old multiple organ donors

Exclusion criteria:
recipient had already had a transplant

ANALYSIS

Primary outcome measure:
not specified

Secondary outcome measure(s):
Delayed graft function DGF
Serum creatinine
Urinary output
Post transplantation dialysis

Method of assessing outcomes:
univariate analyses with Mann-Whitney test and chi-square test to assess differences between groups were used. Graft survival was calculated using Kaplan Meier analysis.

CHARACTERISTICS OF PARTICIPANTS

	University of Wisconsin cold storage solution				Celsior cold storage solution				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Age- donor (years)	88	-	52.9	17.6	99	-	48.6	18.8	4.3	2.66	0.108[a]
Age years -recipient	88	-	46.6	11.4	99	-	46.9	11.7	-0.3	1.69	0.859[a]
DONOR terminal creatinine	88	-	1	0.5	99	-	1.1	0.8	-0.1	0.0965	0.301[a]
DONOR urinary output per hour (mL)	88	-	193.3	139.6	99	-	221.3	165.3	-28	22.3	0.211[a]
RECIPIENT Panel reactive antibodies	88	-	8	12	99	-	12.6	19.3	-4.6	2.32	0.049[a]

Notes
[a] *student's t-test (calculated by reviewer)*

RESULTS

	University of Wisconsin cold storage solution				Celsior cold storage solution				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
A mismatches	88	-	1.4	-	99	-	1.1	-	0.3	-	[b]
Acute rejection	88	13	-	-	99	12	-	-	-	-	-
B mismatches	88	-	1.1	-	99	-	1.3	-	-0.2	-	[b]
Cold ischemia (hours)	88	-	16.7	5	99	-	16.5	6.6	0.2	0.851	0.814[b]
DGF	88	30	-	-	99	31	-	-	1.09	1.23	0.686[a]
DR mismatches	88	-	0.8	-	99	-	0.8	-	0	-	[b]
Graft survival (2 year)	88	66	-	-	99	83	-	-	0.895	1.08	0.134[a]
Number of rejection episodes before discharge	88	-	-	-	99	-	-	-	1.22	1.45	0.595[a]
Post -operative dialysis	88	-	1.9	3.5	99	-	1	3.3	0.9	0.499	0.073[b]
Warm ischaemic time (mins)	88	-	35.1	14.2	99	-	38.3	14.1	-3.2	2.07	0.124[b]
COLD ISCHAEMIA > 17 HOURS											
Creatinine (mg/dL at discharge)	41	-	2.2	1.5	45	-	1.9	1.08	0.3	0.284	0.294[b]
Creatinine day 1 (mg/dL)	41	-	7.08	2.4	45	-	6.2	2.1	0.88	0.488	0.075[b]
Creatinine day 15 (mg/dL)	41	-	3.2	2.2	45	-	2.7	2.02	0.5	0.457	0.277[b]
Creatinine day 3 (mg/dL)	41	-	6.2	3.3	45	-	5.1	3.4	1.1	0.723	0.132[b]
Creatinine day 5 (mg/dL)	41	-	5.3	3.4	45	-	4.6	3.3	0.7	0.724	0.336[b]
Creatinine day 7 (mg/dL)	41	-	4.7	3.4	45	-	4.2	3.3	0.5	0.724	0.492[b]
DGF	41	18	-	-	45	18	-	-	1.1	1.29	0.714[a]
Post-transplantation dialysis rate	41	-	3.9	-	45	-	2.9	-	1	-	[b]
Urinary output discharge (mL/24hrs)	41	-	1754	1153	45	-	1971	1210	-217	255	0.397[b]
Urine output day 1 (mL/24hrs)	41	-	1568	1549	45	-	2265	2575	-697	454	0.128[b]
Urine output day 15 (mL/24hrs)	41	-	1731	1121	45	-	1924	1236	-193	254	0.449[b]
Urine output day 3 (mL/24hrs)	41	-	1622	1477	45	-	1633	1472	-11.2	318	0.972[b]
Urine output day 5 (mL/24hrs)	41	-	1627	1671	45	-	1730	1138	-104	311	0.740[b]
Urine output day 7 (mL/24hrs)	41	-	1651	1228	45	-	1824	1174	-172	260	0.509[b]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *student's t-test (calculated by reviewer)*

STORAGE OF DONATED KIDNEYS: Data Extraction

Faenza et al. (2001)

ASSESSMENT OF STUDY QUALITY

1. **Are the study aims clearly described and focused?**
   YES
2. **Is study design appropriate to answer these aims?**
   YES
3. **Are there explicit inclusion and exclusion criteria for the study?**
   YES
4. **Are methods of randomisation adequate?**
   NOT REPORTED
5. **Was there concealed randomised allocation?**
   UNCLEAR
6. **Are sample characteristics adequately described?**
   YES
7. **Are there significant differences between the cohorts?**
   NO
8. **Was the follow up time adequate for outcomes to change?**
   YES
9. **Do analyses attempt to control for confounders?**
   CAN'T TELL
10. **Is there a power calculation?**
    CAN'T TELL
11. **Is the sample size sufficient?**
    NOT ANALYSED
12. **Is primary outcome measure objective?**
    OBJECTIVE
13. **Are secondary outcome measures objective?**
    OBJECTIVE
14. **Were outcome assessors blind to exposure status?**
    CAN'T TELL
15. **Are drop-out rates similar between intervention and controls?**
    YES
16. **was analysis by ITT**
    NOT REPORTED
17. **Inter centre variability reported?**
    NO
18. **Are the results generalisable?**
    YES
19. **Was ethical approval given?**
    NOT REPORTED
20. **Were all groups treated similarly?**
    YES
21. **Were all participants accounted for?**
    YES

STORAGE OF DONATED KIDNEYS: Data Extraction

Moers et al. (2009)

DESIGN

Study design:
Prospective multi-centre RCT

Country (countries):
Netherlands, Belgium, Germany

Number of centres:
-

Recruitment dates:
Nov 2005- Nov 2006

Length of follow-up:
1 year

Source of funding:
Organ Recovery Systems

ARM(S)

ARM 1:
LifePort
Intervention: Machine perfusion
Number enrolled: 336

ARM 2:
University of Wisconsin and some HTK
Intervention: Cold storage
Number enrolled: 336

UW was the preferred cold storage solution but HTK was allowed, data were not disaggregated

PARTICIPANTS

Number enrolled:
1086

Attrition / dropout:
Excluded post randomisation & prior to storage: donor procdure cancelled = 28, one or both kidneys not transplantable = 140, combined organ offer =2, other reasons =40

MP exclutions: kidney rejected at transplant centre =4, technical failure of MP = 7, due to exclusion of contralateral organ = 10, death of contralateral organ recipient = 1, contralateral organ lost to follow up = 1.

Cold storage exclusions: kidney rejected at transplant centre = 10, due to exclusion of contralateral organ = 11, recipient died one day after transplantation (not related to transplant) = 1, lost to follow up = 1.

Inclusion criteria:
Deceased donors ≥16 years providing kidney pairs
BSD and DCD, Maastricht categories III & IV
kidney pairs must go to different recipients

Exclusion criteria:
Donors > 60 years
Multiple organ transplant of recipient
Only one kidney from a donor transplanted

Recipients
non-transplant related death in first week after transplant

ANALYSIS

Primary outcome measure:
Delayed graft function DGF

Secondary outcome measure(s):
Primary non-function
Duration of DGF
Serum creatinine
Hyperkaliemia
Calcineruin inhibitor toxicicty
Duration of hospital stay
Acute rejection
Graft survival - 1 year
Patient survival - 1 year

Method of assessing outcomes:
The study is powered to detect a 10% change in DGF at 80% with p<0.05, giving an expected sample size of N = 300.
The data will be analysed using posterior stratification of preservation time, HLA matches, recent PRA level, recipient age, 1st/retransplant, lenth of time on dialysis,donor type and donor age.
Correlation of perfusate function to post-transplant graft funtion and survival analysis.
There will also be a cost-benefit analysis with reference to graft outcome and survival.
Fischers exact test used for discrete variables
Mann-Whitney test used for continuous variables

DATA WERE NOT ANALYSED AS ITT

DGF: any dialysis requirment within 7 days post transplant
Paired desgin; one kidney in the donor randomised to machine perfusion and the other automatically to cold storage. Randomisation was carried out by Eruo Transplant at donor using block randomisation.

CHARACTERISTICS OF PARTICIPANTS

	LifePort				University of Wisconsin and some HTK				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Age years -recipient	336	-	53[e]	-	336	-	52[c]	-	1	-	[h]
Cold ischaemic time (hours)	336	-	15[g]	-	336	-	15[f]	-	0	-	[h]
Discard rate @ recipient centre	336	-	-	-	336	-	-	-	0.4	1.8	0.105[a]
Discard rate due to kidney quality @ recipient centre	336	4	-	-	336	10	-	-	-	-	-
HLA mismatches	336	54	-	-	336	50	-	-	1.08	1.2	0.670[a]
Pre-Tx dialysis duratation (years)	336	-	4.5[d]	-	336	-	4.4[b]	-	0.1	-	[h]
Previous transplants	336	77	-	-	336	71	-	-	1.08	1.16	0.576[a]
PANEL REACTIVE ANTIBODIES											
>84%	336	4	-	-	336	3	-	-	1.3	1.51	0.524[a]
0-5 %	336	297	-	-	336	304	-	-	0.977	1.03	0.380[a]
6-84%	336	35	-	-	336	29	-	-	1.22	1.12	0.082[a]

Notes
[a] *chi-square test (calculated by reviewer)*
[b] *MEDIAN range (0.19-24)*
[c] *MEDIAN range (2 -70)*
[d] *MEDIAN range (0.15-18)*
[e] *MEDIAN range (11-79)*
[f] *MEDIAN range (2.5-29.7)*
[g] *MEDIAN range (3.5-26.3)*
[h] *student's t-test (calculated by reviewer)*

STORAGE OF DONATED KIDNEYS: Data Extraction

Moers et al. (2009)

Characteristic	N	k	Mean	SD
Age- donor (years)	336	-	51[i]	-
DONOR BSD	336	294	-	-
DONOR DCD	336	42	-	-

Notes

[i] *range (16 -81)*

RESULTS

	LifePort				University of Wisconsin and some HTK				Comparison		
Outcome	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
Acute rejection within 14 days	336	44	-	-	336	46	-	-	0.957	1.22	0.821[a]
CNI toxicity within 14 days	336	21	-	-	336	19	-	-	1.11	1.36	0.744[a]
Creatinine clearance @ day 14 (ml/mol)[b]	336	-	42	-	336	-	40	-	-	-	-
DGF	336	70	-	-	336	89	-	-	0.787	1.15	0.085[a]
DGF duration (days)[b]	336	-	10	-	336	-	13	-	-3	-	[c]
Functional DGF	336	77	-	-	336	101	-	-	0.762	1.14	0.036[a]
Graft survival (12 months)	336	329	-	-	336	316	-	-	1.04	1.02	0.011[a]
Graft survival (6 months)	336	329	-	-	336	319	-	-	1.03	1.02	0.038[a]
Hospitalisation (days)[b]	336	-	19	-	336	-	18	-	1	-	[c]
Patient survival (12 months)	336	326	-	-	336	326	-	-	1	1.01	1.000[a]
Patient survival (6 months)	336	329	-	-	336	329	-	-	1	1.01	1.000[a]
PNF	336	7	-	-	336	16	-	-	0.438	1.56	0.056[a]
DGF											
Cold ischemia (hours)	336	-	-	-	336	-	-	-	1.07	0	.002
DCD donor vs. BSD donor	336	-	-	-	336	-	-	-	10.1	0	<0.001
Donor age (yrs)	336	-	-	-	336	-	-	-	1.03	0	.003
Duration of pre-transplant dialysis (yrs)	336	-	-	-	336	-	-	-	1.07	0	.06
HLA mismatches	336	-	-	-	336	-	-	-	1.11	0	.17
MP vs. CS	336	-	-	-	336	-	-	-	0.63	0	.02
PRA levels (0-5%, 6-84%, >84%)	336	-	-	-	336	-	-	-	1.01	0	.38
Recipient age (yrs)	336	-	-	-	336	-	-	-	1.01	0	.21
Re-transplant vs. first transplant	336	-	-	-	336	-	-	-	2.75	0	<0.001
GRAFT FAILURE											
Cold ischemia (hours)	336	-	-	-	336	-	-	-	1.04	0	0.28
DCD donor vs. BSD donor	336	-	-	-	336	-	-	-	1.32	0	0.67
Donor age (yrs)	336	-	-	-	336	-	-	-	1.06	0	0.002
Duration of pre-transplant dialysis (yrs)	336	-	-	-	336	-	-	-	0.97	0	0.63
HLA mismatches	336	-	-	-	336	-	-	-	1.22	0	0.15
MP vs. CS	336	-	-	-	336	-	-	-	0.46	0	0.05
Recipient age (yrs)	336	-	-	-	336	-	-	-	0.97	0	0.07
Re-transplant vs. first transplant	336	-	-	-	336	-	-	-	1.85	0	0.13

Notes

[a] *chi-square test (calculated by reviewer)*

[b] *MEDIAN*

[c] *student's t-test (calculated by reviewer)*

ASSESSMENT OF STUDY QUALITY

1. **Are the study aims clearly described and focused?**

   YES

2. **Is study design appropriate to answer these aims?**

   YES

3. **Are there explicit inclusion and exclusion criteria for the study?**

   YES

4. **Are methods of randomisation adequate?**

   YES - Block randomisation, separate lists for each region. Kidneys were allocated from a central office. Switiching allowed between arms if MP not possible for technical reasons

5. **Was there concealed randomised allocation?**

   YES

6. **Are sample characteristics adequately described?**

   YES

STORAGE OF DONATED KIDNEYS: Data Extraction

Moers et al. (2009)

7. **Are there significant differences between the cohorts?**
   NO
8. **Was the follow up time adequate for outcomes to change?**
   YES
9. **Do analyses attempt to control for confounders?**
   YES - MATCHED COHORTS
10. **Is there a power calculation?**
    YES
11. **Is the sample size sufficient?**
    YES
12. **Is primary outcome measure objective?**
    OBJECTIVE
13. **Are secondary outcome measures objective?**
    OBJECTIVE
14. **Were outcome assessors blind to exposure status?**
    YES
15. **Are drop-out rates similar between intervention and controls?**
    YES
16. **was analysis by ITT**
    NO
17. **Inter centre variability reported?**
    NO
18. **Are the results generalisable?**
    YES
19. **Was ethical approval given?**
    YES
20. **Were all groups treated similarly?**
    CAN'T TELL
21. **Were all participants accounted for?**
    CAN'T TELL

STORAGE OF DONATED KIDNEYS: Data Extraction

Watson (2006)

DESIGN

Study design:
Prospective multi-centre RCT

Country (countries):
UK

Number of centres:
5

Recruitment dates:
-

Length of follow-up:
5 years

Source of funding:
Novartis Pharma and Organ Recovery Systems

ARM(S)

ARM 1:
LifePort
Intervention: Machine perfusion
Number enrolled: 45

43 kidneys were actually treated with MP

ARM 2:
University of Wisconsin cold storage solution
Intervention: Cold storage
Number enrolled: 45

47 kidneys were actually treated with CS

PARTICIPANTS

Number enrolled:
93

Attrition / dropout:
3 discarded: 1= anatomical reasons, 2=failed to receive allocated treatment

Inclusion criteria:
DCD donors
> 17 years olf

Exclusion criteria:
Recipients are excluded if they show:
Positive crossmatch
Previous non-renal transplant
No consent

ANALYSIS

Primary outcome measure:
Delayed graft function DGF

Secondary outcome measure(s):
Measured at 3 and 12 months and 5 years:
Creatinine reduction ratio day 0 -5 (CRR05) <30%
Creatinine reduction ratio day 1 -2 (CRR2) <30%
Mean creatinine reduction ratios
Patient survival
Graft survival
Renal function measured using calculated GFR
Non function rate
Time to last dialysis post transplant
Acute rejection incidence
Cost comparison at one year

Method of assessing outcomes:
The kidneys from each donor are randomised to each treatment group, by the left or right kidney and by order of transplant.
A power calcuation showed that 205 participants would give 90% power to detect a difference between the groups in a fixed sample size analysis. However, for ethical reasons a sequential design was adopted where patients are recruited until there is sufficient evidence, based on the primary endpoint, to reject the null hypothesis ie that there is no difference between the two methods of preservation.
Randomisation is through the duty office of Organ Donation and Transplantation Directorate of NHS Blood and Transplant who also monitor data collection and determine the end of the study.
Analysis was by ITT. As the data are paired McNemar's extact test is used to determine if graft function is associated with the method of kidney storage.

DGF - the need for dialysis in the first 7 days following kdiney transplantation

CHARACTERISTICS OF PARTICIPANTS

	LifePort				University of Wisconsin cold storage solution				Comparison		
Characteristic	**N**	**k**	**Mean**	**SD**	**N**	**k**	**Mean**	**SD**	**Est**	**SEM**	**P**
RECIPIENT											
Age years	45	-	50.3	13.2	45	-	48.6	13.9	1.7	2.86	0.553[b]
First transplant	39	-	-	-	40	-	-	-	-	-	-[a]
Gender (n male)	31	-	-	-	33	-	-	-	-	-	-[a]
Height (cm)	45	-	168.9	10.5	44	-	172.6	9.6	-3.7	2.13	0.086[b]
Months of pre-transplant dialysis	44	-	52.8	53.8	45	-	44.4	39.1	8.4	9.99	0.403[b]
Re-graft	6	-	-	-	5	-	-	-	-	-	-
Sensitised	4	-	-	-	5	-	-	-	-	-	-[a]
Serum albumin at transplant (gm/l)	45	-	39	5.4	45	-	39.1	6.4	-0.1	1.25	0.936[b]
Serum calcium (corrected for albumin) pre-tx (mmol/l)	44	-	2.3	0.1	44	-	2.3	0.2	0	0.0337	1.000[b]
Serum creatinine pre-transplant (umol/l)	44	-	701.7	292	44	-	677.8	227.2	23.9	55.8	0.669[b]
Serum urea at transplant (mmol/l)	44	-	17.1	8.1	44	-	15.3	7	1.8	1.61	0.268[b]
weight (kg)	45	-	73.2	13.5	45	-	77	14.6	-3.8	2.96	0.203[b]
RECIPIENT ETHNICITY											
Non-white	4	-	-	-	7	-	-	-	-	-	-[a]
White	41	-	-	-	38	-	-	-	-	-	-[a]
RECIPIENT HLA MISMATCH LEVEL											

Watson (2006)

Characteristic	LifePort				University of Wisconsin cold storage solution				Comparison		
	N	k	Mean	SD	N	k	Mean	SD	Est	SEM	P
3	27	-	-	-	23	-	-	-	-	-	-[a]
4	6	-	-	-	7	-	-	-	-	-	-[a]
RECIPIENT TYPE OF DIALYSIS AT ADMISSION											
Haemodialysis	28	-	-	-	28	-	-	-	-	-	-[a]
No dialysis	3	-	-	-	3	-	-	-	-	-	-[a]
Peritoneal dialysis	14	-	-	-	14	-	-	-	-	-	-[a]

Notes

[a] *chi-square test (calculated by reviewer)*

[b] *student's t-test (calculated by reviewer)*

RESULTS

(Academic-in-confidence information removed)

ASSESSMENT OF STUDY QUALITY

1. Are the study aims clearly described and focused?
   YES
2. Is study design appropriate to answer these aims?
   YES
3. Are there explicit inclusion and exclusion criteria for the study?
   YES
4. Are methods of randomisation adequate?
   YES - kidneys are randomised to treatment group and order of transplantation
5. Was there concealed randomised allocation?
   YES
6. Are sample characteristics adequately described?
   YES
7. Are there significant differences between the cohorts?
   NO
8. Was the follow up time adequate for outcomes to change?
   YES - this is an ongoing 5 year trial for which we have 3 month data
9. Do analyses attempt to control for confounders?
   N/A

STORAGE OF DONATED KIDNEYS: Data Extraction

Watson (2006)

9. **Do analyses attempt to control for confounders?**
   N/A
10. **Is there a power calculation?**
    YES
11. **Is the sample size sufficient?**
    YES
12. **Is primary outcome measure objective?**
    OBJECTIVE
13. **Are secondary outcome measures objective?**
    OBJECTIVE
14. **Were outcome assessors blind to exposure status?**
    CAN'T TELL
15. **Are drop-out rates similar between intervention and controls?**
    YES - no drop out at 3 months
16. **was analysis by ITT**
    YES
17. **Inter centre variability reported?**
    YES - this is planned but not yet available
18. **Are the results generalisable?**
    YES
19. **Was ethical approval given?**
    YES
20. **Were all groups treated similarly?**
    YES
21. **Were all participants accounted for?**
    YES