

REVISED HABSelect GANTT - 11/14/34 [Vs 25/08/2015] Selection of sperm for Assisted Reproductive Treatment by prior hyaluronic acid binding: increasing live birth

outcomes and reducing miscarriage rates. Hyaluronan Binding Sperm selection (HABSelect).

EXTENSION PERIOD

Milestones	Pre-Funding Release			Year 1												Year 2												Year 3												Year 4												Year 5							
	-7	-6	-5	-4	-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51
Pre-set up 8 months (scheduled for 3 months)	[Gantt bars for Pre-set up 8 months]																																																										
HABSelect Clinical Trial:	[Gantt bars for HABSelect Clinical Trial]																																																										
Pre-set up 8 months (scheduled for 3 months)	[Gantt bars for Pre-set up 8 months]																																																										
PCTU started HABSelect part time	[Gantt bar]																																																										
HABSelect Trial Manager Appointment (full time)	[Gantt bar]																																																										
Core TMG Established	[Gantt bar]																																																										
TMG Established with Regional Clinical Advisors	[Gantt bar]																																																										
Finalise Protocol	[Gantt bar]																																																										
Ethics Submitted	[Gantt bar]																																																										
Ethics Approval	[Gantt bar]																																																										
R&D Approvals initiated	[Gantt bar]																																																										
Set up 9 months(scheduled for 3 months)	[Gantt bars for Set up 9 months]																																																										
NIHR Contracts Finalised - Triggers Official start date	[Gantt bar]																																																										
Site Feasibility - reorganisation of recruitment targets & sites as only including NHS/MHS Self funding patients (i.e. excluding private patients)	[Gantt bar]																																																										
Finance & Contracting:PCTU & Sponsor/University of Leeds Roles & Responsibilities Delegation Agreement	[Gantt bar]																																																										
Finance & Contracting: Co-I Sub contracts; recruiting site agreements (amended to NHS patient-only targets); lab agreements; biobanking	[Gantt bar]																																																										
CLRN Service Support Costs Approved (West Yorkshire CLRN)Assumption-Private patients not eligible for SSC)	[Gantt bar]																																																										
Ethics, R&D & Site Approvals	[Gantt bar]																																																										
Establish case report forms (CRFs)	[Gantt bar]																																																										
Establish trial database	[Gantt bar]																																																										
Establish 24 hour web-based randomisation system	[Gantt bar]																																																										
HABSelect team identify candidates for TSC, DMEC	[Gantt bar]																																																										
Launch Site Initiation Meetings -Training in trial operations	[Gantt bar]																																																										
Training of HABSelect Team in ICSI & HA Binding score (Hydak slide)	[Gantt bar]																																																										
Randomisation(M8-M34)(scheduled for 21 months) With extension to M35	[Gantt bars for Randomisation]																																																										
First Phase Sites Open	[Gantt bar]																																																										
Second Phase Sites recruiting	[Gantt bar]																																																										
First Eligibility screening (beginning of December 2013)	[Gantt bar]																																																										
First couple randomisation and ICSI (beginning of February 2014)	[Gantt bar]																																																										
Couple Eligibility screening N=10,000	[Gantt bar]																																																										
Couple Recruitment & Consent 21 months at each site N=3730	[Gantt bar]																																																										
Patient Randomisation & ICSI Procedure (Occurs - 6-8 weeks after consent)	[Gantt bar]																																																										
Trial Phase- Follow Up (10 months i.e. pregnancy duration) M8-M48	[Gantt bars for Follow Up]																																																										
Clinical Follow-up (& outcome collection) P ICSI Sample Collection	[Gantt bars for Clinical Follow-up]																																																										
Safety Monitoring	[Gantt bars for Safety Monitoring]																																																										
HA binding score (Hydak slide)	[Gantt bars for HA binding score]																																																										
Mechanistic Study (24 months) M11-M34	[Gantt bars for Mechanistic Study]																																																										
Comet Assay AO Assay Aniline Blue Assay CMA3 Assay n=900	[Gantt bars for Comet Assay]																																																										
Cytology All samples N=3730	[Gantt bars for Cytology]																																																										
Biobanking of residual sperm (delayed)	[Gantt bars for Biobanking]																																																										
Data analysis & write-up (6 months)	[Gantt bars for Data analysis]																																																										
Statistical Analysis Plan	[Gantt bar]																																																										
Programming, Maintenance & Report Generation	[Gantt bar]																																																										
Clinical data management	[Gantt bar]																																																										
Comet Assay AO Assay Aniline Blue Assay CMA3 Assay	[Gantt bars for Comet Assay]																																																										
HA binding Score in relation to clinical outcomes Analysis	[Gantt bars for HA binding Score]																																																										
Anticipated Safety Reports for DMEC	[Gantt bars for Safety Reports]																																																										
Final Report & Publications	[Gantt bar]																																																										
Trial Management Meetings	[Gantt bars for Trial Management Meetings]																																																										
Trial Management Group	[Gantt bar]																																																										
Trial Steering Committee	[Gantt bar]																																																										
Data Monitoring & Ethics Committee	[Gantt bar]																																																										