Site ID: Date (DD/MM/YY): Participant Trial ID Number:
AVURT
Aspirin for Venous Ulcers: Randomised Trial
Participant 'weekly' data collection file
COVER SHEET
For Study Investigator Completion
Date patient was randomised (DD/MM/YY)

1. Date patient was r	andomised (DD/MM/Y	Y)				
Signature of nurse comple (randomisation date)	eting question 1					
Please print name						
Date form completed						
2. Date patient took first dose of IMP (DD/MM/YY)						
3. What time of day	does the participant to	ake their AVURT capsu	les? Please circle			
Morning	Afternoon	Evening	Varies			
Signature of nurse completing questions 2 and 3.						
Please print name						
Date form completed						

Site ID: Date (DD/MM/YY): / Participant	ID No:	
AVURT		
Aspirin for Venous Ulcers: Randomised Trial		
Participant 'weekly' data collection file		
For Study Investigator Completion		
Week number: 1		
If the participant is not seen this week, and therefore you are unable to complete th collection file, please give reason(s) in the table below and fax this page <u>only</u> along Section 8 and/or the adverse event log <u>if appropriate</u> , to the YTU, Fax number		
	Yes	No
No scheduled appointment		
Participant missed appointment*		
*2a. Was the appointment missed due to an AE or AR that has not been		
reported previously?		
If you answered 'Yes' to this question, please complete Section 8 of this form and the adverse event log		
*2b Date of missed appointment (DD/MM/YY)		
Change of circumstances		
If you answered 'Yes' to this question, please complete form F (Change to		
study status)	_	
4. Other**		
**If other please give reason:		
The nurse completing the above table OR the weekly file to sign here please		
Signature of nurse completing form		
Please print name		
Date form completed		

AVURT Data Collection File week 1 Version 1.2 Final 08.06.15 Page 1 of 4

Site ID:	Date (DD/MM/YY):		/ 🔲	Participant ID No:	
Sectio	<u>n 1</u>				
1.	Is the questionnaire being completed (please	circle one a	nswer)		
	In presence of participant		0	ver the telephone <sup>‡</sup> .	
<sup>‡</sup> .lf con	npleted over the telephone please go directly t	o section 2			
				Yes	No <sup>†</sup>
2.	Please confirm a photograph of the reference	ulcer has be	een take	en	
	† If NO places trace the ulear and confirm the	ulaar aisa in	2 222		cm <sup>2</sup>
	<sup>†</sup> If <b>NO</b> please trace the ulcer and confirm the	uicer size ir	CIII		
Sectio	<u>n 2</u>				
				Yes	No
1.	Has the Reference Ulcer healed?				
	If No please go to section 3.				
	If Yes please answer questions 1a to 1b and	ax this form	to York	Trials Unit today	
Di	O/ -11				
Please	answer 'Yes' to one of the following question	100.000	No	Ĭ	
10 10 1	his the first appointment that the ulcer has bee	Yes	No	If 'yes' form D to be co	mploted in
	ed as healed?	#II		2 weeks time*	impleted in
assess	ed as flealed?			2 Weeks tillle	
1h If v	ou answered 'yes' to question 1a please ensu	re that form	D is to h	ne completed in week r	10.3
15. II y	ou answered yes to question to please ensu	ie tilat lollil	D 13 to t	be completed in week i	
Sectio	n <u>3</u>				
1.	How often has the participant taken their AVU	JRT capsule	s (300m	ng Aspirin/placebo per d	ay) this
	week? (please circle one reason)				
	Every day Most days	So	me days	s Not a	t all
2.	If participant has not taken their AVURT caps	ules each da	ay pleas	se record reasons (pleas	se circle all
	that apply)				
Illness	Couldn't swallow capsule   Forgot   Couldn	't open conta	ainer	Medic advised to stop	Other**
				taking*	
*Recor	d details of this here	**If other	olease s	specify here	

If participant has stopped taking medication due to an adverse reaction please complete section 8 of this form and the adverse event log

Site ID: Date (DD/MIM/YY): / / / /	Participant ID No:
Section 4	
1. In the montining of commonth, we said in a community of the second	Vee* No No
Is the participant currently receiving compression therapy?	Yes* No
1a, If YES*, has the participant complied with their treatment (please	circle one statement below)
Fully Partially*	Not at all*
*If partially or not at all please record reason	
Has the level of compression changed since the Baseline form	Yes* No
was completed?	
	*If YES please complete form A
Section 5	
Г	I
2 Harden Carlos Control of the Contr	Vt
3. Has the type of primary dressing or bandage changed since the Baseline form was completed?	Yes* No
the baseline form was completed:	
	*If YES please complete form B
Section 6	
Approximately how many other wound consultations (excluding	
this one) has the participant had in the last week?	
Add additional information (such as if the participant is an inpatient)	
Sastian 7	
Section 7	
How many ulcers are present on the REFERENCE LEG	
,	

Site ID:	Date (DD/MM/YY):		/	Participant ID No:		

### Section 8

	Yes	No
1. Has the participant experienced any adverse events		
1a. If yes, was this a serious adverse event (SAE)?		
2. Has the participant experienced any adverse reactions		
2a. If yes, was this a serious adverse reaction (SAR)?		

If YES to any of these questions, please follow the Adverse Event SOP as detailed in the site file All Adverse Events whether serious or not will be recorded in the clinic notes in the first instance. A record must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs and SARs must be notified to the sponsor immediately when the investigator becomes aware of the event (within 24 hours). Refer to JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the sponsor via fax on or E-mailed to . If patients stop taking IMP due to an AE or SAE please complete Form F

### Section 9

1.	Please confirm participant has been asked if there is a change to ANY, medications they take?	
2.	Has there been a change to concomitant medication since baseline questionnaire completion*	

Thank you for completing this form Please fax to:

Site ID:	Date (DD/MM/YY): / /	Participant ID No:	
	AVURT		

# Aspirin for Venous Ulcers: Randomised Trial Participant 'weekly' data collection file For Study Investigator Completion

Week number:

2, 3, 7-24, 26,27

If the participant is not seen this week, and therefore you are unable to complete the weekly data collection file, please give reason(s) in the table below and fax this page only alongside Form F, Section 8 and/or the adverse event log if appropriate, to the YTU, Fax number

	Yes	No
No scheduled appointment		
Participant missed appointment*		
*2a. Was the appointment missed due to an AE or AR that has not been		
reported previously?		
If you answered 'Yes' to this question, please complete Section 8 of this form		
and the adverse event log		
*2b Date of missed appointment (DD/MM/YY)		
3. Change of circumstances		
If you answered 'Yes' to this question, please complete form F (Change to		
study status)		
4. Other**		
**If other please give reason:		
The nurse completing the above table or the weekly file to sign here please		
Signature of nurse completing form		
Please print name		
Date form completed		

Six ID					1 1
Site ID: Date (DD/MM/YY):		/	Participa	ant ID No:	
Section 1					
1. Is the questionnaire being completed (	please circle	one answer)			
In presence of participant		0\	er the telepho	ne <sup>‡</sup>	
*If completed over the telephone please go to	Section 2				
				Yes	$No^{\dagger}$
2. Please confirm a photograph of the refe	erence ulcer	has been take	n		
<sup>†</sup> If <b>NO</b> please trace the ulcer and confi	rm the ulcer	size in cm²			cm <sup>2</sup>
Section 2					
				Vaa	Na
Has the Reference Ulcer healed				Yes	No
THE RESIDENCE OF THE PROPERTY					
If NO please go to Section 3.	al amal fav thi	fama ta Vanle	Tuiala Illuit taal		
If YES please answer questions 1a to 1	d and lax this	s form to York	Trials Unit too	ay	
Please answer 'yes' to one of the following qu	estions				
The second of th		Yes No			
1a. Is this the first appointment that the ulcer h	as been		If 'yes' form D	to be com	pleted in
assessed as healed?			2 weeks time	*	
1b. Was the ulcer first assessed as healed at I	ast		If 'yes' form D	to be com	pleted
week's appointment?			next week*		
1c. Was the ulcer first assessed as healed 2 w	/eeks		If 'yes' form D	to be com	pleted
ago?			today.		
					eek no.
1d. If you answered 'yes' to question 1a or 1b	please state	week number	that form D is	to be	
completed					
Section 3					
1. How often has the participant taken the	eir AVURT ca	psules (300m	g Aspirin/place	bo per day	) this
week? (please circle one reason)  Every day  Most days		Some days		Not at a	II .
If participant has not taken their AVUR	T cansules of				
that apply)	i vapsules e	acii day pieas	e record reaso	iis (picase	on ole all
	Couldn't open	container	Medic advise	d to stop	Other**
3 3 3 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	v andetstranspac S 2501€6 7.255		taking*		2007 2004503035
*Record details of this here	**If (	ther please s	197.0		

Site ID: Date (DD/MM/	YY):	Particip	ant ID No:				
If participant has stopped taking medication due to an adverse reaction please complete section 8 of this form and the adverse event log.							
Section 4							
Is the participant currently re	eceiving compression therapy?	Yes*	No				
1a, If YES*, has the participant	complied with their treatment (please	circle one stat	ement below)				
Fully	Partially**	N	ot at all**				
**If partially or not at all please red	cord reason						
Has the level of compression completed?	n changed since this form was last	Yes*	No				
Section 5		*If YES pleas	se complete form A				
Has the type of primary dressing or bandage changed since this form was last completed?  No  No  No							
Section 6		*If YES pleas	se complete form B				
Approximately how many ot this one) has the participant	her wound consultations (excluding had in the last week?						
Add additional information (such as if the participant is an inpatient)							
Section 7							
How many ulcers are present	nt on the REFERENCE LEG						

Site ID:		Date (DD/MM/YY):		/		/		Participant ID No:		
										•

### Section 8

	Yes	No
<ol> <li>Has the participant experienced any adverse <u>events</u> that have not been previously reported?</li> </ol>		
1a. If yes, was this a serious adverse event (SAE)?		
2. Has the participant experienced any adverse <u>reactions</u> that have not been previously reported?		
2a. If yes, was this a serious adverse reaction (SAR)?		

If YES to any of these questions, please follow the Adverse Event SOP as detailed in the site file All Adverse Events whether serious or not will be recorded in the clinic notes in the first instance. A record must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs and SARs must be notified to the sponsor immediately when the investigator becomes aware of the event (within 24 hours). Refer to JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the sponsor via fax on or E-mailed to . If patients stop taking IMP due to an AE or

SAE please complete Form F

## Section 9

		Yes	No
1.	Please confirm participant has been asked if there is a change to ANY, non-trial, medications they take?		
2.	Has there been a change to concomitant medication since last reported (including doses and frequency of existing medication)?*		
YES	S please complete Form C ensuring a named doctor is consulted		

Thank you for completing this form Please fax to:

Site ID: Date (DD/MM/YY): / / Partic	ipant ID No:	$\overline{\Box}$
AVURT		
Aspirin for Venous Ulcers: Randomised Tr	ial	
Participant 'weekly' data collection file		
For Study Investigator Completion		
Week number: 4-6		
If the participant is not seen this week, and therefore you are unable to complet collection file, please give reason(s) in the table below and fax this page only al Section 8 and/or the adverse event log if appropriate, to the YTU, Fax number		
	Yes	No
No scheduled appointment		
2. Participant missed appointment*		
*2a. Was the appointment missed due to an AE or AR that has not been		
reported previously?		
If you answered 'Yes' to this question, please complete Section 8 of this for and the adverse event log	m	
*2b Date of missed appointment (DD/MM/YY)		
Change of circumstances		
If you answered 'Yes' to this question, please complete form F (Change t	:o	
study status)		
4. Other**		
**If other please give reason:		

Please print name

The nurse completing the above table or the weekly file to sign here please

Signature of nurse completing form

Site ID:	Date (	DD/MM/	YY):				Pa	articipa	nt ID N	o:	
Section	n 1									_	-
		o boing o	omplotod	/places sir	ala ana ar	acumr)					
	Is the questionnaire In present			(please cili	cie one ai		er the te	alanhan	,o <sup>‡</sup>		
‡If comr	oleted over the telepl			rtly to Sectio	n 2		rei the te	Siepriori			
ii comp	neted over the telepi	none pica.	se go an e	ctry to occito	11 2						
									Yes	s	No <sup>†</sup>
2.	Please confirm a	photogra	ph of th	e reference	e ulcer ha	s been	taken				
							Ti-				
											_
1	f NO please trace t	he ulcer a	and confi	rm the ulcer	r size in cr	m <sup>2</sup>			(4)		cm <sup>2</sup>
									-		
0 4:											
Section	<u>n 2</u>										
									Yes		No
1.	Has the Reference	I llcar ha	aled						165		NO
	If NO please go to s	- 2005 - 4005 - 1000 -	DEFAUTOUR V								
	ii ito picase go to t										
Î	If YES please answ			1d and fax	this form	to York	Trials U	Init toda	ıv		
	If YES please answ answer 'ves' to on	er questi	ons 1a to		this form	to York	Trials U	Init toda	ıy		
	If YES please answ answer 'yes' to on	er questi	ons 1a to		this form	to York	Trials U	Init toda	ny		
Please	answer 'yes' to on	er questi e of the f	ons 1a to ollowing o	questions.	1					omp	eleted in
Please 1a. Is th	-	er questi e of the f	ons 1a to ollowing o	questions.	1			form D		omp	oleted in
Please  1a. Is the assessed	answer 'yes' to on	er questi e of the formers	ons 1a to ollowing of the ulcer	has been	1		If 'yes'	form D	to be c		
1a. Is the assessed 1b. War	answer 'yes' to on his the first appointr ed as healed?	er questi e of the formers	ons 1a to ollowing of the ulcer	has been	1		If 'yes'	form D s time* form D	to be c		
1a. Is the assessed 1b. Waweek's	answer 'yes' to on his the first appointr ed as healed? s the ulcer first asso	er questi e of the forment that essed as	ons 1a to ollowing of the ulcer healed a	has been	1		If 'yes' 2 week If 'yes' next we	form D s time* form D	to be c	omp	leted
1a. Is the assessed 1b. Waweek's	answer 'yes' to on his the first appointred as healed? s the ulcer first asso appointment?	er questi e of the forment that essed as	ons 1a to ollowing of the ulcer healed a	has been	1		If 'yes' 2 week If 'yes' next we	form D s time* form D eek*	to be c	omp	leted
1a. Is the assessed 1b. Waweek's 1c. Was	answer 'yes' to on his the first appointred as healed? s the ulcer first asso appointment?	er questi e of the forment that essed as	ons 1a to ollowing of the ulcer healed a	has been	1		If 'yes' 2 week If 'yes' next we If 'yes'	form D s time* form D eek*	to be c	omp	leted
1a. Is the assessing 1b. Waweek's 1c. Wasago?	answer 'yes' to on his the first appointred as healed? s the ulcer first asso appointment?	er questi e of the forment that essed as essed as	ons 1a to ollowing of the ulcer healed a healed 2	t last weeks	Yes	No	If 'yes' 2 week If 'yes' next we If 'yes' today.	form D ss time* form D eek* form D	to be c	omp	eleted
1a. Is the assessing 1b. Waweek's 1c. Wasago?	answer 'yes' to on his the first appointred as healed? s the ulcer first assa appointment? s the ulcer first assa ou answered 'yes' t	er questi e of the forment that essed as essed as	ons 1a to ollowing of the ulcer healed a healed 2	t last weeks	Yes	No	If 'yes' 2 week If 'yes' next we If 'yes' today.	form D ss time* form D eek* form D	to be c	omp	eleted
1a. Is the assessed 1b. Waweek's 1c. Wasago?	answer 'yes' to on his the first appointred as healed? s the ulcer first asso appointment? s the ulcer first asso but answered 'yes' to	er questi e of the forment that essed as essed as	ons 1a to ollowing of the ulcer healed a healed 2	t last weeks	Yes	No	If 'yes' 2 week If 'yes' next we If 'yes' today.	form D ss time* form D eek* form D	to be c	omp	eleted
1a. Is the assessing the second of the secon	answer 'yes' to on his the first appointred as healed? s the ulcer first asso appointment? s the ulcer first asso but answered 'yes' to	er questi e of the forment that essed as essed as	ons 1a to ollowing of the ulcer healed a healed 2	t last weeks	Yes	No	If 'yes' 2 week If 'yes' next we If 'yes' today.	form D ss time* form D eek* form D	to be c	omp	eleted
1a. Is the assessed b. Was week's 1c. Was ago?  1d. If you comple	answer 'yes' to one his the first appointred as healed? s the ulcer first assorate appointment? s the ulcer first assorate ulcer first appointre ulcer first appointre ulcer first assorate ulcer firs	er questi e of the forment that essed as essed as o questio	ons 1a to ollowing of the ulcer healed a healed 2 n 1a or 1	t last weeks b please sta	Yes ate week	No	If 'yes' 2 week If 'yes' next we If 'yes' today.	form D is time* form D eek* form D m D is to	to be c to be c to be c	omp omp	oleted oleted ek no.
1a. Is the assessed 1b. Was week's 1c. Was ago?  1d. If you complete Section 1.	answer 'yes' to on his the first appointred as healed? s the ulcer first asso appointment? s the ulcer first asso but answered 'yes' to	rer questi e of the forment that essed as essed as o questio	the ulcer healed a healed 2 n 1a or 1	t last weeks b please sta	Yes ate week	No	If 'yes' 2 week If 'yes' next we If 'yes' today.	form D is time* form D eek* form D m D is to	to be c to be c to be c	omp omp	oleted oleted ek no.
1a. Is the assessed 1b. Was week's 1c. Was ago?  1d. If you complete Section 1.	answer 'yes' to on his the first appointred as healed? s the ulcer first asso appointment? s the ulcer first asso ou answered 'yes' t ted  How often has the	ment that essed as essed as o questio	the ulcer healed a healed 2 n 1a or 1	t last weeks b please sta	Yes ate week	No	If 'yes' 2 week If 'yes' next we If 'yes' today.  that form	form D is time* form D eek* form D m D is to	to be c to be c to be c	omp We	ek no.
1a. Is the assessing the section of	answer 'yes' to on his the first appointred as healed? s the ulcer first asso appointment? s the ulcer first asso ou answered 'yes' t ted higher and the week? (please circ	rer questi e of the forment that essed as essed as o questio participar le one rec	the ulcer healed a healed 2 n 1a or 1	t last weeks b please sta	Yes  ate week i	No number s (300m	If 'yes' 2 week If 'yes' next we If 'yes' today.  that form	form D ss time* form D eek* form D m D is to	to be controlled to be	omp  We	ek no.
1a. Is the assessed 1b. Was week's 1c. Was ago?  1d. If you completed Section 1.	answer 'yes' to on his the first appoint ed as healed? s the ulcer first asso appointment? s the ulcer first asso ou answered 'yes' t ted h 3 How often has the week? (please circ. Every day	rer questi e of the forment that essed as essed as o questio participar le one rec	the ulcer healed a healed 2 n 1a or 1	t last weeks b please sta	Yes  ate week i	No number s (300m	If 'yes' 2 week If 'yes' next we If 'yes' today.  that form	form D ss time* form D eek* form D m D is to	to be controlled to be	omp  We	ek no.

If participant has stopped taking medication due to an adverse reaction please complete section 8 of this form and the adverse event log.

\*Record details of this here

\*\*If other please specify here

Site ID: Date (DD/MM/	YY): / / /	Participant ID No:
Section 4		
Is the participant currently re	eceiving compression therapy?	Yes* No
1a, If YES*, has the participant	complied with their treatment (please	e circle one statement below)
Fully	Partially*	Not at all*
*If partially or not at all please rec	ord reason	
Has the level of compressio completed?	n changed since this form was last	Yes* No
Section 5		*If YES please complete form A
Has the type of primary dress     this form was last completed	ssing or bandage changed since d?	Yes* No
Section 6		*If YES please complete form B
Approximately how many ot this one) has the participant	her wound consultations (excluding had in the last week?	
Add additional information (such	as if the participant is an inpatien	t)
Section 7		
How many ulcers are present	nt on the REFERENCE LEG	

Site io:     Date (DD/MIN/YY):     /     /     Participani	LID NO:	
Section 8		
	Yes	No
1. Has the participant experienced any adverse events that have not been		
previously reported?		
1a. If yes, was this a serious adverse event (SAE)?		
2. Has the participant experienced any adverse <u>reactions</u> that have not been previously reported?		
2a. If yes, was this a serious adverse reaction (SAR)?	,	
If YES to any of these questions, please follow the Adverse Event SOP as detail All Adverse Events whether serious or not will be recorded in the clinic notes in the first ins must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs and SARs must be not sponsor immediately when the investigator becomes aware of the event (within 24 hours). JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the on or E-mailed to . If patients stop taking IMF or SAE please complete Form F  Section 9	stance. A tified to the Refer to sponsor	record ne via fax
	Yes	No
1. Please confirm participant has been asked if there is a change to ANY, non-trial,		
medications they take?		
2. Has there been a change to concomitant medication since last reported (including		
doses and frequency of existing medication)?*		
*If YES please complete Form C ensuring a named doctor is consulted		
Visual Analogue Score Instructions for completing the scale: Place a cross in one of the boxes below to indicate the intensity of pain from you over the last 24 hours, ranging from no pain to the worst pain imaginable.  1. How intense has the pain from your leg ulcer(s) been over the past 24 hours.		)
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90	95 100	)
No Pain		st pain jinable
(For office use only)		

Thank you for completing this form Please fax to:

AVURT Data Collection File week 4-6 Version 1.2 Final 08.06.15 Page 4 of 4

AVURT		
Aspirin for Venous Ulcers: Randomi	ised Trial	
Participant 'weekly' data collection	on file	
For Study Investigator Comple	tion	
Week number: 25		
the participant is not seen this week, and therefore you are unable to	o complete the weekly	/ data
		m F,
ection 8 and/or the adverse event log <u>if appropriate,</u> to the YTU, Fax		m F,
ection 8 and/or the adverse event log <u>if appropriate</u> , to the YTU, Fax  1. No scheduled appointment	number	
ection 8 and/or the adverse event log <u>if appropriate,</u> to the YTU, Fax	number Yes	
1. No scheduled appointment 2. Participant missed appointment*  *2a. Was the appointment missed due to an AE or AR that has not I reported previously?  If you answered 'Yes' to this question, please complete Section 8 or	number Yes been	
1. No scheduled appointment 2. Participant missed appointment *2a. Was the appointment missed due to an AE or AR that has not I reported previously?  If you answered 'Yes' to this question, please complete Section 8 ond the adverse event log	number Yes been	
Participant missed appointment*  *2a. Was the appointment missed due to an AE or AR that has not I reported previously?	number Yes been	
1. No scheduled appointment 2. Participant missed appointment*  *2a. Was the appointment missed due to an AE or AR that has not be reported previously?  If you answered 'Yes' to this question, please complete Section 8 and the adverse event log  2b Date of missed appointment (DD/MM/YY)	humber Yes been of this form	
1. No scheduled appointment 2. Participant missed appointment **  *2a. Was the appointment missed due to an AE or AR that has not be reported previously?  If you answered 'Yes' to this question, please complete Section 8 on the adverse event log  2b Date of missed appointment (DD/MM/YY)  3. Change of circumstances	humber Yes been of this form	

Signature of nurse completing form	, ,
Please print name	
Date form completed	

Site ID:		YY):	/_			Partio	ipan	t ID No:	
Section	<u>n 1</u>								
1.	Is the questionnaire being c	ompleted	(please c	ircle one an	swer)				
	In presence of part					er the tele	phon	e <sup>‡</sup>	
<sup>‡</sup> If comp	oleted over the telephone plea	se go dire	ctly to Sect	ion 2					
								Yes	No
2.	Please confirm a photograp	h of the r	eference u	lcer has be	en take	n			
									*
3.	Please trace the ulcer and c	onfirm th	e ulcer siz	e in cm²					cm <sup>2</sup>
Section	n 2								
								Yes	No
1.	Has the Reference Ulcer he	aled							
)	If NO please go to Section 3								
1	If YES please answer questi	ons 1a to	1d and fa	x this form	to York	Trials Unit	toda	y	
Please	answer 'yes' to one of the fe	ollowing	questions.	_					
				Yes	No				
1a. Is t	his the first appointment tha	t the ulce	r has beer	n		If 'yes' for	m D	to be co	mpleted in
assess	ed as healed?					2 weeks t	ime*		
1b. Wa	s the ulcer first assessed as	healed a	t last			If 'yes' for	m D	to be co	mpleted
week's	appointment?					next week	<b>(*</b>		
1c. Was	s the ulcer first assessed as	healed 2	weeks			If 'yes' for	m D	to be co	mpleted
ago?						today.			
								1	Neek no.
1d. If yo	ou answered 'yes' to questio	n 1a or 1	b please s	tate week r	number	that form [	) is to	be be	
comple	ted								
Section	<u>n 3</u>								
1	How often has the participar	nt taken t	heir AV/IIR	T cansules	(300m	a Aspirin/n	laceh	n ner d	av) this
	week? (please circle one re-		HOII AVOIN	. oupsules	100011	a respirit/p	.aoet	o per u	Ay) 11113
		Most day	s	Son	ne days			Not at	all
2.	If participant has not taken t						ason		
	that apply)							U	
Illness	Couldn't swallow capsule	Forgot	Couldn't	open conta	iner	Medic adv	/ised	to stop	Other**
						taking*			

If participant has stopped taking medication due to an adverse reaction please complete section 8 of this form and the adverse event log.

\*\*If other please specify here

\*Record details of this here

Site ID: Date (DD/MIM/	YY):	Participant i	D No:				
Section 4							
Is the participant currently re	Yes*	No					
1a, If YES*, has the participant complied with their treatment (please circle one statement below)							
Fully	Partially*	Not a	at all*				
*If partially or not at all please rec	ord reason						
		Ī					
2 Has the level of compression	n changed since this form was last	Yes*	No 🗌				
completed?	in changed since this form was last	163					
Contraction Contraction States							
		*If YES please of	complete form A				
Section 5							
Has the type of primary dres	ssing or bandage changed since	Yes*	No				
this form was last complete		Ш					
•							
		*If YES please of	complete form B				
Section 6							
Approximately how many of	her wound consultations (excluding						
this one) has the participant							
Add additional information (such	as if the participant is an inpatien	t)					
Section 7							
		_	1				
How many ulcers are prese	nt on the REFERENCE LFG						
How many diocis are prese	JIO INEI EINEINOE EEO						

Site ID:		Date (DD/MM/YY):		/[	/[	Part	icipant ID No:		

### Section 8

	Yes	No
<ol> <li>Has the participant experienced any adverse <u>events</u> that have not been previously reported?</li> </ol>		
1a. If yes, was this a serious adverse event (SAE)?		
2. Has the participant experienced any adverse <u>reactions</u> that have not been previously reported?		
2a. If yes, was this a serious adverse reaction (SAR)?		

If YES to any of these questions, please follow the Adverse Event SOP as detailed in the site file All Adverse Events whether serious or not will be recorded in the clinic notes in the first instance. A record must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs and SARs must be notified to the sponsor immediately when the investigator becomes aware of the event (within 24 hours). Refer to JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the sponsor via fax on or E-mailed to . If patients stop taking IMP due to an AE or SAE please complete Form F

#### Section 9

1.	Please confirm participant has been asked if there is a change to ANY, non-trial,	
	medications they take?	
2.	Has there been a change to concomitant medication since last reported (including	
	doses and frequency of existing medication)?*	

At week 25 please collect the AVURT medication from the participant. Return this medication to St Georges pharmacy

Thank you for completing this form Please fax to:

Site ID: D	ate (DD/MM/YY): /	/ P	articipant ID No:			
AVURT: Form A Changes to compression therapy						
Week number:		Date of comp Day Monti				
What level of con	What level of compression is the new treatment aiming for? Please tick					
≤19mmHG	Medium 20-39mmHG	High 40mmHG & above	None			
Signature of nurse filling in form A						
Please print name						

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Site ID: Date (DD/MM/YY): Part	ticipant ID No:					
AVURT: Form B						
Changes to dressing or bandages Page 1 of 2						
Week number:  Date of completing Day Month	etion Year					
What is the primary dressing (that is in contact with the ultre table below  If no dressing, places state 'no dressing' in 'other' box below.	cer)? Select one in					
If no dressing, please state 'no dressing' in 'other' box below						
New Dressing	Coloot one					
New Dressing	Select one					
Silver-containing	Select one					
Silver-containing lodine-containing	Select one					
Silver-containing Iodine-containing Honey-containing	Select one					
Silver-containing Iodine-containing Honey-containing Alginate	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel Soft polymer	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel Soft polymer Hydrocolloid	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel Soft polymer Hydrocolloid Foam	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel Soft polymer Hydrocolloid	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel Soft polymer Hydrocolloid Foam Basic wound contact (absorbent dressing/low adherence	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel Soft polymer Hydrocolloid Foam Basic wound contact (absorbent dressing/low adherence dressing)	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel Soft polymer Hydrocolloid Foam Basic wound contact (absorbent dressing/low adherence dressing) Film	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel Soft polymer Hydrocolloid Foam Basic wound contact (absorbent dressing/low adherence dressing) Film	Select one					
Silver-containing Iodine-containing Honey-containing Alginate Hydrogel Soft polymer Hydrocolloid Foam Basic wound contact (absorbent dressing/low adherence dressing) Film	Select one					

Site ID: Dete (DD/M M/YY): /	Participant ID No:			
AVURT	T: Form B			
Changes to dressing or band	ages CONTINUED page 2 of 2			
Week number:	Date of completion Day Month Year			
What type of bandage is now being used as the primary bandage? Select one in the table below  If no bandage, please state 'no bandage' in 'other' box below				
New bandage	Select one			
Four Layer				
3 layer				
3 layer reduced compression				
Reduced compression				
2 layer hoslery (alming to deliver high con	npression)			
Reduced compression hosiery				
Other (please state)				
Signature of nurse filling in form B				
Please print name				
Esta DELINION				
Date (DD/MM/YY)				

Site ID: Date (	(DD/MM/YY):	/	/ Pai	rticipant ID No:		
AVURT: Form C Changes to medication						
Week number:			Date of compl Day Month	etion Year		
Please complete givi	Please complete giving details of ALL CHANGES to patient's medication					
Name of medication						
Reason for taking/change						
Dose		Frequ				
Start date		End o	late			
Name of medication Reason for						
taking/change						
Dose		Frequ				
Start date		End o	late			
Name of medication						
Reason for taking/change						
Dose		Frequ	iency			
Start date		End	late			
Nome of						
Name of medication						
Reason for						
taking/change						
Dose		Frequ	iency			
Start date		End	late			

· '	AVURT: Form C to medication CONTINUED	
Changes	to medication con mode	
Week number:	Date of completion Day Month Year	
Signature of nurse filling in form (	;	
Please print name		
Date (DD/MM/YY)		
Please pass to the named do that the patient is still eligible.  To be completed by named do		to confirn
that the patient is still eligible To be completed by named d	for participation in AVURT octor to determine eligibility Yes	to confirn
that the patient is still eligible To be completed by named d	for participation in AVURT  octor to determine eligibility  Yes  ges to medication – is the participant	
To be completed by named of Following assessment of the char	for participation in AVURT  octor to determine eligibility  Yes  ges to medication – is the participant	
To be completed by named of Following assessment of the chareligible to continue their participa *If no please specify reasons  *Please confirm the participa medication	for participation in AVURT  octor to determine eligibility  Yes  ges to medication – is the participant	No*
To be completed by named of Following assessment of the chareligible to continue their participa *If no please specify reasons  *Please confirm the participa medication	for participation in AVURT  octor to determine eligibility  Yes  riges to medication – is the participant tion in the AVURT Trial  Int has been informed to stop taking their AV	No*

Date (DD/MM/YY)

Site ID: Date (I	DD/MM/YY):	/	/ Part	ticipant ID No:	
AVURT: Form C Changes to medication Supplementary page(page number)					
Week number:			Date of comple Day Month	etion Year	
Please complete givi	ng details of ALL	CHANGE	S to patient's me	edication	
Name of		· · · · · ·			
medication					
Reason for					
taking/change		Γ			
Dose Start date		End	uency		
Start date		LIIU	uate		
Name of					
medication					
Reason for					
taking/change					
Dose		Freq	uency		
Start date			date		
Name of					
medication					
Reason for					
taking/change		Γ			
Dose Stort data			uency		
Start date	<u> </u>	Ena	date		
Name of					
medication					
Reason for					
taking/change					
Dose		Fred	uency	1	
Start data		End	dato		

Site ID: Date (DD/MM/YY): /	/ Participant ID No:			
AVURT: Form D Reference ulcer healing check/confirmation				
Week number:	Date of completion Day Month Year			
	l assessment of healing as recorded in ata collection file			
Please record the following information				
1. Is the reference ulcer healed? Yes*	No**			
*If YES, Please inform the participant today to stop taking the AVURT medication immediately and arrange for the remaining trial medication to be returned to St George's Research Pharmacy.				
*1a Has the participant been informed to stop	taking the trial medication?			
Yes	No			
*1b Arrange a date and time to call participan study [Note this will not be required if this form				
**If NO, the participant will continue in the patient data in the participant data weekly coll				
**2a. Please confirm a photograph of the reference ulcer/wound site has been taken				
**2b. Please confirm a tracing of the refe	erence ulcer has been made			
Signature of nurse filling in form D				
Please print name				
Date (DD/MM/YY)				

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Site ID: Date (DD/MM/YY): /	/ Participant II	No:					
AVURT: Form E							
	assessment*						
Recuirence	изэсээнген						
Week number:	Date of completion Day Month Year						
*To be completed for all participants in we week 24 or earlier in the trial (nurse to pho participant's ulcer recurs.			in				
1. Is there any new ulcer on the reference	leg Yes** No						
**If YES date of recurrence Day Month Year							
2. Please indicate how notification was re-	ceived Please tick one box be	elow					
2a. Nurse phoned participant in 'week 25'							
2b. Participant telephoned clinic to advise uld	cer has broken down						
2c. Participant seen in clinic and ulcer/wound	site clinically assessed						
2d. Other							
		Yes	No				
3. Has the participant experienced any adverse e point?							
3a. If yes, was this a serious adverse event (SA							
If YES to any of these questions, please follow the Adverse Event SOP as detailed in the site file All Adverse Events whether serious or not will be recorded in the clinic notes in the first instance. A record must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs must be notified to the sponsor immediately when the investigator becomes aware of the event (within 24 hours). Refer to JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the sponsor via fax on or E-mailed to or E-mailed to If patients stop taking IMP due to an AE or SAE please complete Form F							
Signature of nurse filling in form E							
Please print name							
Date (DD/MM/VV)							

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Site ID: Date (DD/MM/YY):	/ Participant ID No:				
AVURT: Form F Change to study status page 1 of 2					
Week number:	Date of completion Day Month Year				
Please complete this form when there	is a change in the status of a participant				
Reasons for change in patient follow-up: (	(Place a cross in the appropriate box)				
Participant is being withdrawn from	m treatment and agrees to further follow up				
Participant is being fully withdraw	n from the study				
Participant is lost to follow up					
Participant is being withdrawn from be used.	m the study and has asked for their data not to				
Reason(s) for withdrawal etc (if known	)				

Site ID: Date (DD/MM/YY): / Participant ID No:				
AVURT: Form F Change to study status CONTINUED page 2 of 2				
Week number:  Date of completion Day Month Year				
Participant has died				
A Serious Adverse Event form has been completed Yes No				
Date of death Day Month Year				
	_			
Signature of nurse filling in form F				
Please print name				
Date (DD/MM/YY)				
	_			
Confirmed by lead PI/medic				
Please print name				
Date (DD/MM/YY)				