Site ID: ☐☐ Screening ID: ☐☐☐☐☐ Date DD/MM/YY ☐☐☐☐☐☐

AVURT

Aspirin for Venous Ulcers: Randomised Trial

Screening
For Study Investigator Completion

Before completing this form please ensure that the patient has signed the consent form indicating their willingness to take part in the trial

I am confident that this information is accurate and complete and I can confirm that the study is being conducted according to protocol and any subsequent amendments and that consent was obtained prior to study entry. Please sign this after the CRF has been completed in full

Signed_____ (Site Principal Investigator)

Print_____ Date signed (DD/MM/YY) ☐☐ ☐☐ ☐☐

Date informed consent obtained (DD/MM/YY) ☐☐ ☐☐ ☐☐

When completed please fax to York Trials Unit on: [redacted]

Instructions for this questionnaire

The following questionnaire contains a series of questions designed to screen patients for participation in the AVURT trial.

Informed consent MUST be obtained prior to any screening procedure, including the completion of this form.

This CRF may be completed by the principal investigator or a delegated member of staff listed on the AVURT Delegation Log. However the details on this form and the eligibility of the patient must be confirmed by the delegated doctor who must sign and date Section G3 of this form and provide their details.

Please complete all sections of the form using the spaces provided and only skip sections if the text directs you to do so.

If the patient is eligible ensure a medically qualified Doctor checks and signs off section G prior to proceeding to AVURT prescribing and randomisation.

If you have further questions please contact a member of the York Trials Unit whose details you will find in the AVURT site information file.

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Section A: Demographic Data

PERSONAL DETAILS OF PATIENT

1. **Date of birth** DD | | MM | | YY | |

2. **Gender** **Male** ☐ **Female** ☐

3. **Has the patient ever smoked?** **Never** ☐ **Current smoker** ☐ **Previous smoker** ☐

SECTION B: Assessment of child bearing potential for MALE and FEMALE participants

1. Is the patient (male or female) of child bearing potential? **Yes** ☐ **No** ☐

A female of child bearing potential is defined as:

- A sexually mature woman (i.e. any woman who has ever experienced menstrual bleeding)
  AND
- Who has not undergone a hysterectomy or who has not been postmenopausal for at least 24 consecutive months (i.e. Who has had menses at any time within the preceding 24 consecutive months)

All males must answer this question

If NO please proceed to Section D

2. If **YES** does the participant agree to use a reliable method of contraception* for the duration of the study and a further six weeks after the last dose of study medication?
   Yes ☐ **No** ☐

*Acceptable methods of contraception are surgical sterilisation, oral, implantable or injectable hormonal method, intrauterine devices or barrier contraceptives

If **NO** the patient is ineligible for participation in AVURT. Please proceed directly to section F and complete

- If YES and Male please proceed straight to section D
- If Yes and Female continue to section C

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SECTION C: Assessment of breastfeeding FEMALE patients only

1. Is the patient currently breastfeeding? **Yes** ☐ **No** ☐

If **YES** the patient is ineligible for participation in AVURT. Please proceed directly to section F and complete

If **NO** please proceed to section D

SECTION D: Inclusion Criteria

The following criteria MUST all be answered YES for the patient to be included in the trial:		**Yes**	**No**
1	At least one chronic venous leg ulcer - where chronic venous leg ulceration is defined as any break in the skin which has either: a) been present for more than six weeks, or b) occurred in a person with a history of venous leg ulceration. Ulcers will be considered purely venous if clinically no other aetiology was suspected. For this the ulcer must be venous in appearance (i.e. moist, shallow, of an irregular shape) and lie wholly or partially within the gaiter region of the leg. If the patient has more than one ulcer we will choose the largest ulcer as the 'index' lesion for purposes of the analysis.		
2	Ulcer area greater than 1cm^2		
3	Have had an ankle brachial pressure index (ABPI) ≥ 0.8 taken within the previous three months or, where ABPI is incompressible, have had PAD excluded in another form of assessment such as including peripheral pulse examination / toe pressure / duplex ultrasound in combination with clinical judgement to be used to exclude PAD		
4	Aged greater than or equal to 18 years (no upper age limit)		
5	Informed consent		
6	Ulcer duration greater than 6 weeks or prior history of venous ulceration		

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SECTION E: Exclusion Criteria

The following criteria MUST all be answered NO for the patient to be included in the trial:		**Yes**	**No**
1	Unable to provide consent		
2	Unwilling to provide consent		
3	Foot (below the ankle) ulcer		
4	A leg ulcer of non-venous aetiology (e.g. Arterial)		
5	Ankle-brachial pressure index (ABPI) <0.8 or, where ABPI is not compressible, PAD cannot be excluded by other assessments		
6	Regular concomitant aspirin		
7	Previous intolerance of aspirin/contraindication to aspirin (decision made according to the prescribers' clinical judgement)		
8	Is the patient on any prohibited medication: Oral anticoagulants including coumarins (warfarin & acenocoumarol) and phenindione, dabigatran, rivaroxaban and apixaban, heparin, clopidogrel, dipyridamole, probenecid, sulfinpyrazone & iloprost		
9	Known lactose intolerance.		
10	Currently participating in another study evaluating leg ulcer therapies.		
11	Another reason that excluded them from participating within this trial (decision made according to the nurses' or prescribers' clinical judgement)*		
12	Previously been recruited in to this trial.		

*Contraindications to Aspirin as listed on the Aspirin SmPC i.e. Aspirin should not be taken by patients with the following conditions:

- Known hypersensitivity to salicylic acid compounds or prostaglandin synthetase inhibitors (e.g. certain asthma patients who may suffer an attack or faint and certain patients who may suffer from bronchospasm, rhinitis and urticaria) and to any of the excipients;
- Nasal polyps associated with asthma (high risk of severe sensitivity reactions).
- Active or history of recurrent peptic ulcer and/or gastric/intestinal haemorrhage or other kinds of bleeding such as cerebrovascular haemorrhage or a past history of ulceration or dyspepsia.
- Haemorrhagic diathesis; coagulation disorders such as Haemophilia and thrombocytopenia
- Patients who are suffering from gout
- Severe hepatic impairment
- Severe renal impairment

SECTION F: Eligibility

1. Are all the inclusion criteria answered YES (section D)? **Yes** ☐ **No** ☐

2. Are all the exclusion criteria answered NO (section E)? **Yes** ☐ **No** ☐

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3. Does the participant meet the inclusion criteria in sections B and C **Yes** ☐ **No** ☐

Patient status (please select only one box in this section)

The patient is eligible and will be included in AVURT ☐ please complete all of section G

The patient is not eligible to be included in AVURT ☐ please complete section G1 and G2 then proceed to section H

The patient is eligible but is to be excluded (state why below) ☐ please complete section G1 and G2 then proceed to section H

SECTION G: Eligibility and medic assessment signoff

1.

	By patient	By Nurse
Consent Form has been signed and dated **(please tick)**		

2. **Form completed by:**

Signature of staff member performing eligibility assessment	
Please print name	
Date	

If ineligible, go to Section H and <u>do not</u> complete question G3 below

Please now pass this form to the named doctor assessor (stated on the delegation log) for their assessment and counter signature, to be completed below, to ensure GCP compliance

3. Confirmation by doctor assessor

	Yes	No*
Confirmation AVURT Screening satisfactory		
***If no please specify reasons**		
Baseline Medication Questionnaire checked to ensure inclusion in AVURT study is not contraindicated		
***If no please specify reasons**		

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Signature of doctor assessor	
Please print name	
Date (DD/MM/YY)	

If the patient is eligible for inclusion in AVURT proceed to randomisation

Instructions to the doctor assessor:

- sign the AVURT prescription and fax to St George's pharmacy [redacted]*
- photocopy the prescription and file in patient notes
- Ensure the original signed prescription is posted to the Sponsor Pharmacy to facilitate release of AVURT study medication to the patient

*NB All AVURT prescribers must be listed on the delegation log copy held with St George's Pharmacy with a sample signature

SECTION H: If patient is not to proceed to AVURT randomisation

- retain this form and return to York trials Unit following the procedure in the AVURT trial file

If the individual(s) completing this screening form has any further comments regarding this screening visit please enter them here:
