AARDVARK: Screening Visit Worksheet

Screening ID: _____

Date of visit: _____

Informed consent form completed? Yes ☐ No ☐

(If No, please ensure that the patient has consented to the trial/completed a consent form before continuing with the screening visit)

Inclusion/Exclusion Checklist

Inclusion	
Is the patient willing and able to give written informed consent?	Yes ☐ No ☐
Is the patient aged at least 55 years?	Yes ☐ No ☐
Does the patient have an AAA 3 to 5.4 cm in diameter by internal or external measurement according to ultrasound?	Yes ☐ No ☐
Does the patient have a systolic BP <150mmHg?	Yes ☐ No ☐
Exclusion	
Is the patients already required to take either an ACE-inhibitor or a calcium channel blocker or Angiotensin II blocker (ARB) and cannot be converted to diuretic therapy and/or a 5mg dose of amlodipine for control (i.e. SBP < 150mmHg) of their BP?	Yes ☐ No ☐
Does the patient have known renal artery stenosis (>50%), or with a serum creatinine of >180µmol/L	Yes ☐ No ☐
Is the patient unable to give informed consent	Yes ☐ No ☐
Is the patient too frail to travel for 3-monthly surveillance?	Yes ☐ No ☐
Does the patient have any clinically significant medical condition which, in the opinion of the investigator, may interfere with the study results and or reduce life expectancy to < 2 years	Yes ☐ No ☐
Has the patient participated in another trial of an investigational product or device within the previous 30 days?	Yes ☐ No ☐

Does the patient have a known allergy or sensitivity to perindopril or amlodipine?	Yes ☐	No ☐
Is the patient unable or unwilling to comply with the requirements of the study, in the opinion of the investigator?	Yes ☐	No ☐

Completed by: _____ _____

Name **Signature**

Vital Signs & AAA measurement

BP machine used: Omron ☐ (please photocopy the printout of the BP results)

Pulsecor ☐ (please save the measurements onto a computer)

Time	Pulse	BP measurement 1 (mmHg)	BP measurement 2 (mmHg)	BP measurement 3 (mmHg)
		/	/	/

Is the patient receiving statins?	Yes ☐	No ☐
Has the patient been prescribed indapamide at this visit?	Yes ☐	No ☐
Does this patient require referral to GP for hypertension?	Yes ☐	No ☐
Will this patient be attending a 6wk rescreening?	Yes ☐	No ☐
AAA LONGDITUDINAL internal diameter		cm
AAA LONGDITUDINAL external diameter		cm
AAA TRANSVERSE internal diameter		cm
AAA TRANSVERSE external diameter		cm

Note - Please record the AAA measurements from the previous clinical scan above rather than the AAA measurements obtained for the baseline visit. At least one of these measurements must be entered.

6 week re-screen **N/A** ☐

Date:_____

Time	BP measurement 1 (mmHg)	BP measurement 2 (mmHg)	BP measurement 3 (mmHg)
	/	/	/
Is the patient suitable to continue in the trial based on their BP? (systolic BP < 150mmHg)			Yes ☐ No ☐

Screening ID: _____

General Medical History

Does subject have any clinically relevant past or current medical history conditions? Yes ☐
No ☐

If yes, please complete table below:

Diagnosis	Date of diagnosis (dd/mm/yyyy)	Status (if past, please record end date)	End date (dd/mm/yyyy)
		☐ Ongoing ☐ Past	
		☐ Ongoing ☐ Past	
		☐ Ongoing ☐ Past	
		☐ Ongoing ☐ Past	
		☐ Ongoing ☐ Past	
		☐ Ongoing ☐ Past	
		☐ Ongoing ☐ Past	
		☐ Ongoing	

		☐ Past	
		☐ Ongoing ☐ Past	

Smoking and Alcohol History

Current smoker	Yes ☐ No ☐ If yes, no. of cigarettes per day: _____ If yes, no. of years smoking: _____
Past smoker	Yes ☐ No ☐ If yes, approx. date of stopping : _____ If yes, no. of cigarettes per day: _____ If yes, no. of years smoking: _____
Units of alcohol per week	

Screening ID: _____

Height and Weight

Date of measurements: _____

Time of measurements: _____

Weight (kg)	Height (cm)

Demographics

Date of birth: _____

Age:_____

Ethnicity:	☐ White ☐ Black or Black British specify: _____ ☐ Asian or Asian British specify: _____ ☐ Other, specify: _____

Blood Sample

Date: _____

Was sample taken for **creatinine?**

Yes ☐ Result: _____umol/L No ☐ Reason:
_____

Was sample taken for **electrolytes?**

Yes ☐ No ☐ Reason:
_____

ALL results **signed** and dated by doctor? Yes ☐ No ☐

Concomitant Medication

Does the patient currently take any concomitant medication? Yes ☐ No ☐

(If Yes, please complete the concomitant medication log)

Screening completed by:

_____ _____ _____

Name **Signature** **Date**

AARDVARK Worksheet : Randomisation Visit (Month 0)

Patient ID: _____

Date of visit: _____

Inclusion/Exclusion criteria reviewed: Yes ☐ No ☐ Reason:

_____

Informed consent reviewed: Yes ☐ No ☐ Reason:

_____

Current medical therapies reviewed: Yes ☐ No ☐ Reason:

_____

Screening bloods reviewed: Yes ☐ No ☐ Reason:

_____

Vital Signs & AAA measurement

Time	Pulse	BP measurement 1 (mmHg)	BP measurement 2 (mmHg)	BP measurement 3 (mmHg)
		/	/	/

AAA LONGDITUDINAL internal diameter	cm
AAA LONGDITUDINAL external diameter	cm
AAA TRANSVERSE internal diameter	cm
AAA TRANSVERSE external diameter	cm

Patient randomised via InForm to bottle: _____

(attach print screen to this page)

Patient seen by: _____

Signature: _____

AARDVARK Worksheet : Month 3

Patient ID: _____

Date of visit: _____

Has the patient experienced any adverse events? Yes ☐ No ☐

If yes, please complete an adverse event form.

Has there been any change to the patient's concomitant medications? Yes ☐ No ☐

If yes, please update the concomitant medications form.

Vital Signs & AAA measurement

Time	Pulse	BP measurement 1 (mmHg)	BP measurement 2 (mmHg)	BP measurement 3 (mmHg)
		/	/	/

AAA LONGDITUDINAL internal diameter	cm
AAA LONGDITUDINAL external diameter	cm
AAA TRANSVERSE internal diameter	cm
AAA TRANSVERSE external diameter	cm

Blood Sample

Was sample taken for creatinine & electrolytes?

Yes ☐ Time: _____ No ☐ Reason: _____

Results reviewed and signed by doctor? Yes ☐ No ☐

Confirmation of bottle dispensed: _____

Visit conducted by: _____

Signature: _____

AARDVARK Worksheet : Months 6, 9, 15, 18, 21

Patient ID: _____

Date of visit: _____

Which month is this? : 6 ☐ 9 ☐ 15 ☐ 18 ☐ 21 ☐

Has the patient experienced any adverse events? Yes ☐ No ☐

If yes, please complete an adverse event form

Has there been any change to the patient's concomitant medications? Yes ☐

No ☐

If yes, please update the concomitant medications form

Vital Signs & AAA measurement

Time	Pulse	BP measurement 1 (mmHg)	BP measurement 2 (mmHg)	BP measurement 3 (mmHg)
		/	/	/

AAA LONGDITUDINAL internal diameter	cm
AAA LONGDITUDINAL external diameter	cm
AAA TRANSVERSE internal diameter	cm
AAA TRANSVERSE external diameter	cm

Confirmation of bottle dispensed: _____

Visit conducted by: _____

Signature: _____

AARDVARK Worksheet : Months 12 & 24

Patient ID: _____

Date of visit: _____

Which month is this? : 12 ☐ 24 ☐

Has the patient experienced any adverse events? Yes ☐ No ☐

If yes, please complete an adverse event form

Has there been any change to the patient's concomitant medications? Yes ☐ No ☐

If yes, please update the concomitant medications form

Vital Signs & AAA measurement

Time	Pulse	BP measurement 1 (mmHg)	BP measurement 2 (mmHg)	BP measurement 3 (mmHg)
		/	/	/

AAA LONGDITUDINAL internal diameter	cm
AAA LONGDITUDINAL external diameter	cm
AAA TRANSVERSE internal diameter	cm
AAA TRANSVERSE external diameter	cm

Blood Sample

Was sample taken for creatinine & electrolytes?

Yes ☐ Time: _____ No ☐ Reason: _____

Results reviewed and signed by doctor? Yes ☐ No ☐

Weight (kg)

Questionnaires

Was the EuroQoL questionnaire completed by the patient? Yes ☐ No ☐

If No, reason: _____

Was the Health Resources questionnaire completed by the patient? Yes ☐ No ☐

If No, reason: _____

Confirmation of bottle dispensed: _____ **(12 MONTH VISIT ONLY)**

Visit conducted by: _____

Signature: _____