***Title**: An evaluation of the effect of an angiotensin-converting enzyme (ACE) inhibitor on the growth rate of small abdominal aortic aneurysms*

AARDVARK **Aortic Aneurysmal Regression of Dilation : Value of Ace-inhibition on Ris K**

Objectives:
1. To investigate the hypothesis that an ACE-inhibitor reduces abdominal aortic aneurysm (AAA) growth rate. In a pilot 3-arm randomised controlled trial: The three interventions are ACE-inhibition with perindopril versus equivalent blood pressure reduction with amlodipine (a calcium channel blocker) versus placebo. By comparing the effects in the perindopril and amlodipine arms, this design will permit an evaluation of any blood pressure independent effects of perindopril.
2. Pending results of the pilot trial, to work with the local and National Aneurysm Screening programme to conduct a larger, definitive 3-arm randomised controlled trial, to investigate the hypothesis that blood pressure reduction with an ACE-inhibitor slows the rate of small AAA growth preferentially compared with other antihypertensive agents. Aneurysm-related mortality, morbidity and quality of life will be the major secondary end-points.

The pilot trial will recruit approximately 225 patients from aortic aneurysm screening sites in or near to London. They will be seen and assessed with an ultrasound examination every three months for a period of 24 months.

(i) Inclusion criteria

(ii) All men or women, aged OVER 60 years, with AAA between 3.0 and 5.5 cm and with a systolic BP <150mmHg will be eligible for inclusion in the trial unless they are routinely already receiving an ACE-inhibitor or amlodipine 10mg daily. For patients whose systolic BP is >150mmHg, a 6 week course of the diuretic indapamide SR (1.5mg daily) will be given, with re-evaluation of BP in the 6th week: If the SBP falls to <150mmHg on this medication subjects would then be eligible for inclusion into the study. If this diuretic treatment is not appropriate then 5mgs of amlodipine could be prescribed by the patients GP if not already taking this drug. This would be followed by a six week re-evaluation as above.

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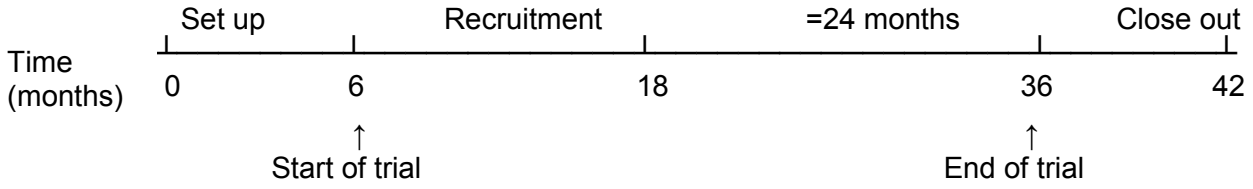
(ii) Exclusion criteria

1. Patients who cannot be converted to diuretic therapy and/or lower doses of amlodipine or patients already taking an angiotensin II antagonist (ARB) for the treatment of blood pressue.
2. those with known renal artery stenosis (>50%), or with a serum creatinine > 180umol/L on routine testing.
3. those unable to give informed consent
4. those too frail to travel for 3-monthly surveillance will be excluded.
5. Any clinically significant medical condition which, in the opinion of the investigator, may interfere with the study results;
6. Participation in another trial of an investigational product or device within the previous 30 days;
7. Known allergy or sensitivity to perindopril or amlodipine
8. Unable or unwilling to comply with the requirements of the study, in the opinion of the investigator.

	Local sceening centre staff	Screen & Consent Project co-ordinator And medical investigator	Randomisation Project co-ordinator	Treatment Project co-ordinator							
Visit	**-2 Suitable patients identified and contacted**	**-1** AAA 3.0-5.4cm? SBP<150mmHg ?	**1 (Baseline) Either 1 week after blood test or 6 weeks after starting indapamide**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Months		-2 to 0.25	0	3	6	9	12	15	18	21	24
Inclusion & exclusion criteria		**X**	**check**								
Informed consent		**X**	**check**								
Demography		**X**									
Past medical history		**X**									
Current medical therapies		**X**	**check**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Ultrasound of AAA	AAA 3.0-5.4cm?	**review**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Blood pressure		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Adverse events				**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Pill count				**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Blood for creatinine and electrolytes		**X**	**review**	**X**			**X**				**X**
Blood for lipid profile		**X**	**review check lipid lowing prescribed**								
EuroQoL, health resource questionnaire							**X**				**X**

Project Timetable and Milestones



Total trial length = 42 months.