ISRCTN51383267 https://doi.org/10.1186/ISRCTN51383267

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

Submission date
14/12/2010

Recruitment status
No longer recruiting

Registration date
16/12/2010

Overall study status
Completed

Last Edited
05/08/2016

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Neil Poulter

Contact details
International Centre for Circulatory Health
59 North Wharf Road
London
United Kingdom
W2 1PG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01118520

Secondary identifying numbers

HTA 08/109/02; CRO 1644/ 01

Study information

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

Acronym
AARDVARK (Aortic Aneurysmal Regression of Dilation: Value of Ace-inhibition on RisK)

Study objectives
To investigate the hypothesis that an angiotensin-converting enzyme (ACE)-inhibitor reduces abdominal aortic aneurysm (AAA) growth rate in a three-arm randomised controlled pilot 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 BP independent effects of perindopril.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0810902
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/51987/PRO-08-109-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
West London Research Ethics Committee 2, 29/11/2010, ref: 10/H0711/80

Study design
Single-blind multicentre placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Asymptomatic abdominal aortic aneurysm

Interventions
This study will be performed at five investigational sites in the UK. This is a randomised, single-blind, multicentre, placebo-controlled study in participants with an systolic blood pressure (SBP) less than 150 mmHg either untreated or on treatment with certain pre-specified background anti-hypertensive medications. The pilot trial will have 3 arms, with patients being randomised to either perindopril (10 mg arginine salt daily) or placebo (primary comparison) or amlodipine (5 mg daily) (secondary comparison). The perindopril and amlodipine doses will have similar effects on blood pressure reduction and hence the secondary comparison will help to inform whether all /any benefits of perindopril are independent of BP reduction. If during the trial an individual patient's aneurysm should reach 5.5 cm in diameter, this patient will be referred back to the vascular surgeons in the normal surveillance programme. This assessment should take place within 2 weeks.

Follow up is 2 years.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Perindopril, amlodipine

Primary outcome measure
Aneurysm growth rate, estimated using multilevel modelling. Patients will have their maximum anterior-posterior aneurysm diameter measured by ultrasonography at 3-monthly intervals, using a dedicated trial co-ordinator.

Secondary outcome measures
The three interventions are ACE-inhibition with perindopril versus equivalent BP 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 BP independent effects of perindopril.

Modelling of time taken for the aneurysm to reach the threshold for intervention (5.5 cm) and formal comparison of the reproducibility of internal and external aneurysm diameters. Quality of life (Euroquol 5D) and health resource questionnaires will be administered after 12 and 24 months of follow up.

Overall study start date
01/03/2011

Completion date
01/03/2014

Eligibility

Key inclusion criteria

1. Willing and able to give written informed consent
2. Men or women, aged at least 60 years
3. AAA 3 to 5.4 cm in diameter according to ultrasound measurement
4. Systolic blood pressure (SBP) less than 150 mmHg (unless they require and are already receiving an ACE-inhibitor or amlodipine 10 mg daily). For patients whose SBP is greater than 150 mmHg, a 6-week course of the diuretic indapamide SR (1.5 mg daily) will be given, with re-evaluation of BP in the 6th week. If the SBP falls to less than 150 mmHg on this medication subjects would then be eligible for randomisation into the study. If this diuretic treatment is not appropriate then 5 mg 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.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
225 participants

Key exclusion criteria
1. Patients who are already required to take either an ACE-inhibitor or a calcium channel blocker or Angiotensin II blocker (ARB) who cannot be converted to diuretic therapy and/or a 5 mg dose of amlodipine for control (i.e., SBP less than 150 mmHg) of their BP
2. Those with known renal artery stenosis (greater than 50%), or with a serum creatinine of greater than 180 µmol/L
3. Those unable to give informed consent
4. Those too frail to travel for 3-monthly surveillance
5. Any clinically significant medical condition which, in the opinion of the investigator, may interfere with the study results and or reduce life expectancy to less than 2 years
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

Date of first enrolment
01/03/2011

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
International Centre for Circulatory Health
London
United Kingdom
W2 1PG

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Faculty of Medicine
G02 Sir Alexander Fleming Building
South Kensington Campus
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016		Yes	No
HRA research summary			28/06/2023	No	No