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Effective Treatments for Thoracic Aortic Aneurysms

Submission date
02/04/2014

Recruitment status
No longer recruiting

Registration date
07/05/2014

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims

The aorta is the main artery that leaves the left side of the heart and carries oxygen-rich blood to the body. An aortic aneurysm is an enlargement (or bulge) of any part of the aorta that results from weakening of the artery wall. Over time, the pressure of the blood flowing in the aorta stretches the weakened area of the wall, creating a risk of rupture or tearing, which can be fatal. Chronic thoracic aortic aneurysm (CTAA) is an enlargement of the thoracic aorta (the part of the aorta that sits inside the chest cavity) that has not yet ruptured but is beyond 50% of normal size. CTAA is a potentially fatal disease and unfortunately the incidence is increasing in western populations. There are estimated to be 3000-8000 new cases of CTAA in the UK each year. The natural history of CTAA is not clearly understood because patients usually remain undiagnosed until they suffer rupture, tearing or death. However, CTAA can be detected prior to such events on imaging investigations, such as CT scans or MRI scans, which have been performed for other conditions.

When a potential aneurysm is detected patients are usually referred to a multidisciplinary medical team (MDT) consisting of heart surgeons, vascular surgeons and interventional radiologists. This team will discuss each individual case, taking into account the patients particular medical condition and the exact nature of their aneurysm, and decide on the best treatment to recommend. While aneurysms remain small, the risks posed by surgical intervention are often greater than the risk of rupture, dissection or death from the aneurysm. Therefore in such cases, patients undergo a watchful waiting (WW) approach whereby they have regular CT or MRI scans to assess the growth of the aneurysm. When aneurysms are identified early (as in WW), or are found in patients unsuitable or unwilling to have surgery, the best medical therapy (BMT) recommended is to control blood pressure, reduce cholesterol, lose weight and stop smoking. Modifying these risk factors can help to slow the rate of aneurysm growth. Above a certain size (usually 5.5 cm for CTAA), treatment either by open surgical repair (OSR) or endovascular stent grafting (ESG) is usually recommended. Treatment may be considered sooner (4.5 cm) in patients with connective tissue disorders, as the aortic wall is weaker and dilates more easily. Open surgery (OSR) is the traditional way to repair aortic aneurysms and it is the method with the longest reported patient follow-up (about 30 years). The operation is invasive, challenging for the patient and associated with considerable risk of death and post-operative complications. ESG is a newer technique which can be performed by keyhole surgery. In this technique, a pre-fabricated tube or stent is delivered into the aneurysm

via arteries in the leg under x-ray guidance. The stent re-lines the aorta from the inside and prevents blood from flowing into the aneurysm, which would cause further dilation and rupture. However, ESG appears to be a more expensive treatment due to the costs of the devices required for the procedure.
Both OSR and ESG come with a risk of complications, such as organ failure, heart attack, stroke, spinal injury and death. It is probable that some patients will be best treated by OSR and others by ESG. OSR tends to be offered to younger patients with less coexisting illness and ESG tends to be offered to older patients who may have several other medical disorders. The best research data available to date suggests that ESG may result in fewer early deaths, less spinal cord injury and fewer short-term complications, but there is much less data on long-term survival compared to OSR. Thus, there is no conclusive research evidence available on the best way to treat CTAA in the UK in terms of both clinical and cost effectiveness. We do not yet have enough information available to provide guidelines on which treatment should be recommended for which particular groups of patients.
This study aims to collect data on thoracic aortic aneurysm patients in order to identify which factors influence the growth rate of aneurysms; to calculate the success rates, complications and cost-effectiveness of ESG and OSR; and to help specialists determine which treatment is best suited to a given patient.

Who can participate?
Patients aged over 18 referred to aortic aneurysm clinics across the UK with a thoracic aortic aneurysm of greater than 4 cm.

What does the study involve?
Following a detailed consent process and adequate time to make an informed decision, patients who are willing to take part in the study will be followed up over a period of 1-5 years after their referral. No additional tests will be undertaken as part of the study, but participants will be asked to provide information on their quality of life and use of NHS and social care services throughout the course of the study and before and after any surgery they might undergo. Participants will also be asked to give permission for their medical records to be examined in detail, in order to collected information about their health status and any treatments that they have throughout the follow-up period. This will include both hospital and general practice records.

What are the possible benefits and risks of participating?
There are no direct benefits to yourself from taking part in this study but the information we get may help to improve the treatment of other people with CTAA in the future.

Where is the study run from?
Our collaborators wide catchment area (currently Cambridge, Liverpool, Papworth, Birmingham, London and Manchester) should allow rapid recruitment into the study. The study is run from Papworth Hospital NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
February 2014 to February 2018

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Sarah Hopkins

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Hopkins

Contact details
Clinical Trials
Papworth Hospital NHS Foundation Trust
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Cambridge
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CB23 3RE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02010892

Secondary identifying numbers
HTA 11/147/03

Study information

Scientific Title
Effective Treatments for Thoracic Aortic Aneurysms: a prospective cohort study

Acronym
ETTAA

Study objectives
This study aims to collect data on patients referred to aortic aneurysm clinics across the UK with a thoracic aortic aneurysm of greater than 4 cm. We aim to analyse all the information collected in order to:

1. Understand the growth rate of aneurysms of chronic thoracic aortic aneurysm (CTAA) and identify which factors influence the growth rate.
2. Clarify the outcomes (procedure success rates and postoperative complications) of endovascular stent grafting (ESG) and open surgical repair (OSR) for CTAA in the current era
3. Estimate the cost-effectiveness of best medical therapy (BMT), ESG and OSR by measuring changes in survival and quality of life of patients compared to the cost of treatment and postoperative patient care
4. Create a risk score that will help specialists determine which intervention (stenting or surgery) is best suited to a given patient

More details can be found here: http://www.nets.nihr.ac.uk/projects/hta/1114703
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/111468/PRO-11-147-03.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 17/12/2013, 13/WM/0507

Study design
Non-randomised; Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Following a detailed consent process and adequate time to make an informed decision, patients who are willing to take part in the study will be followed up over a period of 15 years after their referral. No additional tests will be undertaken as part of the study, but participants will be asked to provide information on their quality of life and use of NHS and social care services throughout the course of the study and before and after any surgical intervention they might have. Participants will also be asked to give permission for their medical records to be examined in detail, in order to collected information about their health status and any treatments that they have throughout the follow-up period (60 months). This will include both hospital and general practice records.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Quality of life (QoL), measured using the EQ-5D-5L; Timepoint(s): every 12 months until study completion

Secondary outcome measures
1. Freedom from death or permanent neurological injury; death or permanent neurological injury will be captured on the case report forms; Timepoint(s): every 12 months until study completion
2. Incremental cost per quality-adjusted life-year gained. Each participant will complete the EQ-5D-5L at regular time intervals. The responses for each participant will be converted into health state utilities using UK population tariffs and used to estimate QALYS using the area under the curve approach. Timepoint(s): every 12 months until study completion
3. Aneurysm growth, measured using CT/MRI scans; Timepoint(s): every 12 months until study completion
4. Costs to the NHS. Resource use will be captured on case report forms (use of secondary care services, incidence and frequency of cost-generating events). For each participant measures of resource use will be combined with unit costs to provide an estimate of cost for that participant. Timepoint(s): every 12 months until study completion
5. Freedom from reintervention; reintervention will be captured on follow-up case report forms; Timepoint(s): every 12 months until study completion

Overall study start date
01/02/2014

Completion date
01/02/2018

Eligibility

Key inclusion criteria
1. CTAA > 4 cm
2. Able to give informed consent
3. Target Gender: Male & Female; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Planned Sample Size: 2200; UK Sample Size: 2200

Key exclusion criteria
1. Intervention required below the level of the celiac axis
2. Acute dissection or malperfusion syndromes (such as myocardial infarction, acute stroke or limb ischaemia)

Date of first enrolment
01/02/2014

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Papworth Hospital NHS Foundation Trust
Cambridge
United Kingdom
CB23 3RE

Sponsor information

Organisation
Papworth Hospital NHS Foundation Trust (UK)

Sponsor details
R&D Unit
Cambridge
England
United Kingdom
CB23 3RE

Sponsor type
Hospital/treatment centre

Website
http://www.papworthhospital.nhs.uk/

ROR
https://ror.org/01qbebb31

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
01/05/2020

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/06/2015		Yes	No
Results article		01/01/2022	01/02/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		02/08/2024	02/08/2024	Yes	No
Results article	Longitudinal health-related quality of life in people with thoracic aortic aneurysms	30/08/2024	12/09/2024	Yes	No