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A comparison study of open surgery, minimal invasive surgery and medical management for complex aortic aneurysms

Submission date
20/12/2016

Recruitment status
No longer recruiting

Registration date
27/02/2017

Overall study status
Completed

Last Edited
01/05/2026

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
An abdominal aortic aneurysm (AAA) is a common condition where the aorta (the main artery that begins at the heart and travels down the torso) begins to bulge and expand at a portion just below the chest, above the level of the navel. In the usual course of events, the bulge expands slowly over many years and can eventually burst (rupture). This results in major internal blood loss often resulting in death and when an emergency lifesaving operation is possible, they have high failure rate. Although the risk of aneurysm rupture is generally low, it starts to increase if the aneurysm exceeds a certain size. A planned operation can be performed to repair the bulging section of aorta to prevent a burst aneurysm. However, not all abdominal aortic aneurysms are equal and technical aspects of aneurysm repair depend upon their location in relation to important branch arteries of the aorta. Over a quarter of aneurysms are classed as juxtarenal aneurysms because they are too close to the arterial branches supplying blood to the kidneys. These aneurysms require more extensive and more complex operations. There are different ways of managing such complex aneurysms and doctors are unsure which method is better. If a patient undergoes surgery, it is likely to be either open repair (where surgery takes place through an opening in the abdomen) or using endovascular techniques (key hole surgery where access to the aorta is gained through another artery, usually in the leg). Endovascular repair usually takes the form of fenestrated endovascular aneurysm repair (fEVAR), the usual method used or standard endovascular repair (Offlabel EVAR), a less complex technique that is originally intended for use in less complex aneurysms. Endovascular techniques have the advantage of a quicker recovery time and a better chance of survival. The aim of this study is to examine how these different treatment methods compare in terms of clinical benefit and utilisation of valuable NHS resources.

Who can participate?
All patients undergoing juxtarenal aneurysm treatment in England

What does the study involve?
Patients who are undergoing open repair, fEVAR, Offlabel EVAR undergo their surgery as planned. They are then monitored by the research team to look at how many have survived after

30 days. Those patients who have an AAA which is not very big are treated without surgery and are also followed up, with scans to see if their aneurysm has grown every six months. Some patients are also asked to complete questionnaires about their quality of life four times over the course of a year.

What are the possible benefits and risks of participating?
There are no notable risks involved with participating.

Where is the study run from?
Royal Liverpool University Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2015 to June 2024

Who is funding the study?
National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?
Miss Charlotte Rawcliffe
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
LCTU202

Study information

Scientific Title

A Risk-adjusted and Anatomically Stratified Cohort Comparison Study of Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneurysms - The UK COMplex AneurySm Study

Acronym
UK-COMPASS

Study objectives
Study Objectives:
1. To compare different treatment strategies for their perioperative mortality and morbidity, corrected for confounding physiological and anatomical characteristics, in order to account for baseline risk and indication biases
2. To identify whether particular physiological and/ or anatomical baseline characteristics are associated with better clinical outcomes or better health economic efficiency using one or other treatment strategy
3. To compare different treatment strategies in terms of overall survival and in terms of treatment failure in the long-term follow-up (stent-graft related complications, secondary interventions, aneurysm-related mortality)
4. To perform cost effectiveness analyses from a broad societal perspective (NHS as well as non-NHS costs) to establish incremental cost effectiveness ratios, comparing different treatment strategies in terms of life years and quality adjusted life years gained
5. To establish the clinical and cost utility of fEVAR and of off-label standard EVAR, in patients who are considered physiologically unfit for OSR, and to compare these against medical management

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Juxtarenal aortic aneurysms

Interventions
This is an observational study of patients being treated within the NHS for juxtarenal aortic aneurysms. No changes have been proposed in the care of patients for the purposes of this study and with the correct approvals and safeguards pseudo- anonymised data and copies of scans will be collected on all patients treated in the NHS for juxtarenal aortic aneurysms.

Surgeons will advise their patients regarding what is considered the best treatment for them, forming cohorts of different treatments. Care pathways in each of the cohorts of this study:

Open Surgical Repair (OSR): Major surgery involving surgically replacing aneurysm with a synthetic graft, through laparotomy. Patients are reviewed to ensure sound healing of surgical wounds and are prepared for return to normal activities, but there is no clinical need for longer term follow-up

Fenestrated Edovascular Aneurysm Repair (FEVAR): Specially designed stent-grafts are placed in the aorta bridging the aorta above the level of the renal arteries to normal arterial segments below the aneurysm. The device comprises openings (fenestrations) to allow blood flow into visceral and renal branches of aorta. This technique avoids laparotomy, leading to quicker recovery and improved perioperative safety.

Off-label EVAR: Judicious use of a less advanced stent-graft designed to repair simpler infrarenal aneurysms (outside the conditions of manufacturers' Instructions for Use). This is termed 'off-label standard EVAR'. Patients undergoing fEVAR and off-label EVAR will require lifelong follow-up by means of a structured surveillance based on scans (CT / ultrasound) and plan X-rays. Clinical practice varies slightly, but usually imaging is done at 1 month and annually thereafter

Medical management 'Operation-deferred': In some patients with comorbidity and aneurysm larger than 55 mm, the risk of death from aneurysm may be considered to be smaller than the risk of death from an elective repair. In such situations, the surgical option may be deferred with a view to proceeding with surgical intervention if the perceived risk of rupture increases through further aneurysm enlargement. Such patients are medically managed with the aim of optimising fitness for surgery. Patients in this cohort undergo periodic ultrasound scans (typically every 6 m) to monitor the aneurysm size as well as best management of comorbidity. Please indicate the differences between the current standard care.

For the quality of life sub-study patients for the selected centres will be approached to take part in the Quality of Life Study. After consent patient will be asked to complete a series of 4 QoL questionnaires (EQ-5D 5SL,A-DQoL,ASRQ, A-TSQ) at 4 time points during their first year after their procedure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Preoperative death, defined as a patient death by any cause occurring within 30 days of surgery, is measured by obtaining data on patients' deaths from the office of national statistics (ONS) and relating any death date to the date of surgery to detainee if death occurred within 30 days.

Key secondary outcome(s))
1. Perioperative complications (morbidity) is measured using routinely collected data obtained through HES which will be collected annually throughout the course of the study
2. Long-term survival is measured using data on patient deaths obtained from the office of national statistics.
3. Secondary intervention in late follow-up is measured using obtained through HES which will be collected annually throughout the course of the study
4. Intensive care usage is measured using obtained through HES which will be collected annually

throughout the course of the study
5. Length of hospital stay is measured using obtained through HES which will be collected annually throughout the course of the study
6. Treatment costs and health economic evaluations are completed using probabilistic modelling to generate estimates of the ICERs and compare the effect of the different structures of treatment provision on different sub-groups of patients
7. Quality of Life is measured using propectively collected EQ5D forms which will be measured at registration and every 3 months following in the subgroup of X patients who are registered into this cohort of the study

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Patients undergoing elective Juxtarenal AAA repair in England; juxtarenal AAA defined and stratified into 4 strata of anatomical complexity as specified in 'Anatomical and Physiological Stratification'
2. Patients with a Juxtarenal AAA 55 mm or larger in size and placed on Medical Management 'Operation-deferred'

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Surgeon-modified stent-grafts and devices
2. Emergency operations (elective operations are distinguished from non-elective ones on NVR)
3. Thoracic or thorcaoabdominal aneurysms (this is a different extent/location of aneurysm disease, requiring different health technology. These treatments are currently being investigated by ETTAA study-HTA 11/147/03. Patients will be included in ETTAA),
4. Aneurysm neck anatomy suitable for standard infrarenal EVAR within IFU of any CE marked device
5. 'Operation Declined Medical Management' patients, due to co-morbidity or patient choice

Date of first enrolment
01/07/2017

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Liverpool University Hospital
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Sponsor information

Organisation
The Royal Liverpool and Broadgreen University Hospitals NHS Trust

ROR
https://ror.org/009sa0g06

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/11/2021	01/05/2026	Yes	No