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Endovascular aneurysm repair (EVAR) trials 1 and 2

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2018	Circulatory System	

Plain English summary of protocol

Background and study aims

Abdominal aortic aneurysm is a condition where the aorta, which is the main artery that leaves the heart and travels down towards the legs, starts to bulge and expand at a section just below the diaphragm, level with the navel. If the bulge continues to expand, it can rupture and this can lead to an emergency operation and often results in death. Studies have shown that if the aneurysm increases to a certain size the risk of rupture, which is generally low, starts to increase and a planned operation can be performed to repair the bulging section of aorta. There are two ways of repairing this section and doctors are unsure which method is better. The open repair method is the tried and trusted method as it has been around for about 50 years and is known to be durable and last for the rest of most patients' lives. However, it is quite a serious operation which generally involves a longer stay in hospital and a slightly higher chance of dying within 30 days of the operation when compared to a new method called EndoVascular Aneurysm Repair (EVAR). This new method is less of a strain on the patient's body which results in a shorter recovery time and a better chance of surviving within the first 30 days after the procedure. The downside of this new procedure is that it is more common for there to be problems following the operation that may require further small procedures to correct them. In some cases, patients are not considered fit enough for the open repair operation as it may be too much of a strain on their body and always requires a general anaesthetic. For these patients, doctors are not sure whether repairing the aneurysm using an EVAR would be best for these patients or whether they would be better treated with regular scans of the aneurysm and given medication to try and improve their fitness. Thus, two studies have been set up to test the new endovascular method in two clinical situations: when the patient is considered fit for an open repair and when the patient is considered unfit for an open repair.

Who can participate?

Patients aged at least 60 with an abdominal aortic aneurysm considered fit for an open repair (EVAR Trial 1) or considered unfit for an open repair (EVAR study 2)

What does the study involve?

In EVAR study 1 participants considered fit for an open repair are randomly allocated to receive either an open repair or the new EVAR procedure, and these two groups are then compared to see how they get on. In EVAR study 2 participants considered unfit for an open repair are

randomly allocated to receive either an EVAR with standard medical treatment or medical treatment alone, and these two groups are then compared to see how they get on. Mortality (number of deaths), quality of life, durability and cost-effectiveness are assessed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Charing Cross Hospital (UK)

When is the study starting and how long is it expected to run for?
July 1999 to August 2016

Who is funding the study?
1. NIHR Health Technology Assessment Programme - HTA (UK)
2. Camelia Botnar Arterial Research Foundation

Who is the main contact?
Prof. Roger Greenhalgh
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Study website
https://www1.imperial.ac.uk/biosurgerysurgicaltechnology/clinical_trials_outcomes/vasculardisease/clinicaltrials/evar_trials/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 95/02/99; HTA 95/02/02; HTA 11/36/46

Study information

Scientific Title
EndoVascular Aneurysm Repair (EVAR) randomised controlled trial in patients with abdominal aortic aneurysm (EVAR 1 and 2)

Acronym
EVAR

Study objectives
Endovascular Aneurysm Repair (EVAR) to exclude Abdominal Aortic Aneurysm (AAA) was introduced in the early 1990s for patients of poor health status considered unfit for major surgery. As the technology has progressed, EVAR has become an alternative choice of treatment for patients considered fit for open repair as it is minimally invasive and generally involves a shorter stay in hospital. The two EndoVascular Aneurysm Repair (EVAR) Trials were instigated to assess the safety and efficacy of endovascular aneurysm repair in the treatment of AAA in terms of mortality, quality of life, durability and cost-effectiveness for patients considered fit (EVAR Trial 1) or unfit (EVAR Trial 2) for open repair.

Added on 27/05/2016:
30-day mortality results were reported in 2004, mid-term results in 2005 and long-term follow-up out to 8 years in 2010. In 2012 the NIHR awarded further funding to extend follow-up out to 15 years because of uncertainty about the long-term durability of EVAR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC North West (original), 28/04/1998
Approval (via an amendment) for extended follow-up to 15 years on 26/01/2011
EVAR Trial 1, ref: 98/8/26
EVAR Trial 2, ref: 98/8/27

Study design
Randomised controlled trial

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular diseases: peripheral arterial disease

Interventions
EVAR Trial 1:
EVAR versus open repair in patients considered fit for open repair

EVAR Trial 2:
EVAR and medical management versus medical management alone in patients considered unfit for open repair

As of 27/05/2016:
Randomisation closed at the end of August 2004 by which time 1656 patients had been enrolled (1252 into EVAR Trial 1 and 404 into EVAR Trial 2). Follow-up was completed in 2015. Data for the 30-day mortality analysis were based upon the 1082 patients randomised to 31/12/2003 (last sentence added 02/06/2016)

Between 01/09/2004 and the publication of mid-term results on 15/06/2005, there was a separate study which randomised 175 patients to either open or endovascular repair (EVAR 1 follow on) and 56 patients to either endovascular repair or no intervention (EVAR 2 follow on) (total 231)

Previous:
Randomisation closed at the end of June 2005 by which time 1486 patients had been enrolled (1082 into EVAR Trial 1 and 404 into EVAR Trial 2). Follow-up continues until the end of 2009.

Intervention Type
Procedure/Surgery

Primary outcome measure
All-cause and aneurysm-related mortality.

Added 27/05/2016:
Follow-up will be until the end of June 2015

Previous:
Follow-up will be until the end of 2009

Secondary outcome measures
As of 27/05/2016:
1. Health Related Quality of Life (HRQL):
1.1. SF-36® Health Survey at 1 year
1.2. Euroqol EQ-5D, assessed annually until the end of 2009
2. Durability of AAA grafts and incidence of complications and re-interventions, followed-up until 2015
3. Costs and cost effectiveness. Data for costs will be collected until 2015
4. Renal function assessed annually until the end of 2009

Please note that methods of assessment for HRQL and the timepoints of assessment for all secondary outcome measures were added as of 06/02/2009 and updated in May 2016.

Previous:
1. Health Related Quality of Life (HRQL):
1.1. SF-36® Health Survey at 1 year
1.2. Euroqol EQ-5D, assessed annually until the end of 2009
1.3. Patient Generated Index at 1 year*
1.4. Stait-Trait Anxiety Index at 1 year*
(*The TMC member with these skills moved to Norway and it was not possible to pursue these outcomes). (added 02/06/2016)
2. Durability of AAA grafts and incidence of complications and re-interventions, followed-up until the end of 2009
3. Costs and cost effectiveness. Data will be collected until the end of 2009.
4. Renal function, assessed annually until the end of 2009

Overall study start date
01/07/1999

Completion date
31/08/2016

Eligibility

Key inclusion criteria
EVAR Trial 1:
1. Males or females
2. Aged at least 60 years
3. Abdominal Aortic Aneurysm (AAA) measuring at least 5.5 cm on a Computed Tomography (CT) scan
4. AAA deemed anatomically suitable for an EndoVascular Aneurysm Repair (EVAR) device
5. Patient considered anaesthetically fit for an open repair

EVAR Trial 2:
1. Males or females
2. Aged at least 60 years
3. Abdominal Aortic Aneurysm (AAA) measuring at least 5.5 cm on a CT scan
4. AAA deemed anatomically suitable for an EndoVascular Aneurysm Repair (EVAR) device
5. Patient considered anaesthetically unfit for an open repair

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants

EVAR 1: Between 1448 and 2205; EVAR 2: 440 (original protocol 1999)

Key exclusion criteria
EVAR Trial 1:
1. Does not match inclusion criteria
2. Not fit for open repair (added 27/05/2016)

EVAR Trial 2:
Patients with hostile abdomen anatomically unsuitable for open repair but anaesthetically well enough for the open operation were excluded.

Date of first enrolment
01/07/1999

Date of final enrolment
31/08/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charing Cross Hospital
London
United Kingdom
W6 8RF

Sponsor information

Organisation
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University/education

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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

Funder Name
Camelia Botnar Arterial Research Foundation

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Other publications	publication on trial design, methodology and progress	01/04/2004		Yes	No
Results article	results on 30-day operative mortality	01/09/2004		Yes	No
Results article	results of EVAR trial 1	01/06/2005		Yes	No
Results article	results of EVAR trial 2	01/06/2005		Yes	No
Results article	results on patient fitness and survival	01/06/2007		Yes	No
Results article	device-specific results of secondary interventions and mortality	01/09/2007		Yes	No
Results article	results on the rupture rate of large abdominal aortic aneurysms	01/01/2008		Yes	No
Results article	results on long-term cost-effectiveness	01/02/2008		Yes	No
Results article	results on rate of cardiovascular events in EVAR trial 2	01/04/2010		Yes	No
Results article	results on endovascular repair in patients physically ineligible for open repair	20/05/2010		Yes	No
Results article	results on endovascular versus open repair	20/05/2010		Yes	No
Results article	results on EVAR versus standard therapy	01/11/2012		Yes	No
Results article	results on the rate and predictability of graft rupture	01/11/2010	02/06/2016	Yes	No
Results article	15-years' follow-up results	12/11/2016		Yes	No
Results article	long-term follow-up results	01/01/2018		Yes	No