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Fascia suture technique compared with a suture-mediated closure device for femoral arterial closure after endovascular aortic repair

Submission date
02/12/2013

Recruitment status
No longer recruiting

Registration date
27/01/2014

Overall study status
Completed

Last Edited
10/04/2015

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
An endovascular aneurysm is a bulge in a blood vessel that is caused by a weakness in the blood vessel wall, usually where it branches. Percutaneous access (access to inner organs via needle-puncture of the skin) for endovascular aneurysm repair (called P-EVAR) using a suture-mediated closure device was first described in 1999. P-EVAR has gained great interest as it may reduce surgery time and decrease time to recovery. However, suture-mediated closure devices increase the procedural cost. The fascia suture technique (FST) was described in 1997 and was first evaluated by our group in 2006. The aim of this study was to investigate whether FST reduces the time and cost of the procedure in comparison to pre-suturing using the Prostar XL percutaneous Vascular Surgical system.

Who can participate?
Patients planned for abdominal endovascular aortic repair (EVAR) or thoracic endovascular aortic repair (TEVAR) for aneurysm or dissection.

What does the study involve?
Participants are randomly allocated to one of two groups:
1. Intervention group: patients will have a fascia suture for access closure
2. Control group: patients will have the Prostar access closure

What are the possible benefits and risks of participating?
The two methods to be compared have been used for several years in routine treatment. These methods have shown a high success rate and severe complications have been rare. Patients are not expected to be at greater risk than if they had not been involved in the study. Improved care through more systematic monitoring was considered as one of the potential benefits for the patients.

Where is the study run from?
The study is run from Örebro University Hospital and Sahlgrenska University Hospital, Göteborg, Sweden.

When is the study starting and how long is it expected to run for?
The recruitment started in June 2006 and the last patient was enrolled in May 2009. The last follow-up took place in December 2009.

Who is funding the study?
Örebro University Hospital, Sweden.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomized two-centre trial to investigate whether the fascia suture technique (FST) can reduce access closure time and procedural costs in comparison to the Prostar technique (Prostar) in patients undergoing endovascular aortic repair and to evaluate the short- and mid-term outcome of both techniques

Study objectives

It was hypothesised that that the fascia suture technique could reduce access closure time and procedural costs in comparison to the Prostar technique in patients undergoing endovascular aortic repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board, regional ethical committee, Uppsala, 07/09/2005, ref.:Dnr 2005: 144

Study design
Randomised two-centre 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Improving surgical performance

Interventions
Participants are randomised to one of the following two groups:
1. Intervention group: patients having a fascia suture for access closure
2. Control group: patients having the Prostar access closure

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 18/06/2014:
Time for access closure, measured with a stopwatch during the primary procedure

Previous primary outcome measures:
1. Time for access closure, measured with a stopwatch during the primary procedure
2. Cost for access closure, measured at the primary procedure and at reported adverse event

leading to an additional procedure and/or hospital stay during the 6-month follow-up period by calculation of material cost (disposables), cost for operative procedure (minutes), ICU stay (hours) and hospital stay (days)

Secondary outcome measures
Current secondary outcome measures as of 18/06/2014:
Previous secondary outcome measures:
1. Technical success of access closure
2. Access-related complications
3. Cost for access closure, measured at the primary procedure and at reported adverse event leading to an additional procedure and/or hospital stay during the 6-month follow-up period by calculation of material cost (disposables), cost for operative procedure (minutes), ICU stay (hours) and hospital stay (days)

Both outcomes will be measured at the operative procedure, at discharge, at 30 days and 6 months follow-up by doctor´s preference and ultrasound at 1 and 6 months.

Previous secondary outcome measures:
1. Technical success of access closure
2. Access-related complications

Both outcomes will be measured at the operative procedure, at discharge, at 30 days and 6 months follow-up by doctor´s preference and ultrasound at 1 and 6 months.

Overall study start date
07/06/2006

Completion date
10/12/2009

Eligibility

Key inclusion criteria
1. All patients planned for abdominal endovascular aortic repair (EVAR) or thoracic endovascular aortic repair (TEVAR) for aneurysm or dissection
2. Planned femoral access
3. Planned for at least 16 F outer diameter of introducer or stent graft system on the main access site

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Aorto-uni-iliac stentgrafts with femoro-femoral bypass
2. Femoral aneurysm
3. Ruptured aneurysms
4. Emergency operations without preoperative ultrasound
5. Ongoing anticoagulation treatment with warfarin

Date of first enrolment
07/06/2006

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
Sweden

Study participating centre
Örebro University Hospital
Örebro
Sweden
SE-70185

Sponsor information

Organisation
Örebro University Hospital (Sweden)

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Sponsor type
Hospital/treatment centre

Website
http://www.orebroll.se

ROR
https://ror.org/02m62qy71

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Örebro University Hospital (Sweden)

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?
Results article	results	01/02/2015		Yes	No