ISRCTN68739781 https://doi.org/10.1186/ISRCTN68739781

# 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?
Dr Thomas Larzon
thomas.larzon@orebroll.se

# Contact information

### Type(s)
Scientific

### Contact name
Dr Thomas Larzon

### Contact details
Department of Cardiothoracic and Vascular Surgery
Örebro University Hospital
Örebro
Sweden
SE-70185
+46 (0)19 602 10 00
thomas.larzon@orebroll.se

# 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)

### Sponsor details
Department of Cardiothoracic and Vascular Surgery
Örebro
Sweden
SE-70185
+46 (0)19 602 10 00
chatarina.lindahl@orebroll.se

### 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 |