Percutaneous access in Endovascular Repair versus Open

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The incidence of wound complications in endovascular aneurysm repair (EVAR). VAS scores will be obtained to objectify the advances of a percutaneous approach. Cultures and wound biopsies will be obtained from every patient. Also cost-effectiveness...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON41463

Source
ToetsingOnline

Brief title
PiERO

Condition

- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
Surgical site infections in aneurysm repair

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Abbott,Sponsoring door Abbott Vascular

Intervention

Keyword: Access, Aneurysm, Percutaneous, Woundinfection

Outcome measures

Primary outcome

the main study endpoint is the risk reduction of the number of surgical site infections (SSI*s) after the use of percutaneous access compared to a surgical cut-down for an EVAR.

Secondary outcome

Secondary endpoint is 1 year postoperatively. VAS scores and bacterial contamination in wound infections will be evaluated.Cultures and biopsies are used.

A correlation is sought between the cultures harvested from the nose and the perineum.

Also cost-effectiveness is questioned in case of a significant difference between the SSI-incidences.

Study description

Background summary

The Prostar XL device has proven a high rate of procedural success (1). Wound complications were absent (2) or appeared in 0.7% (3) of the cases. In open access procedures wound complications vary from 6.3% (www.prezies.nl) to 7.4% (4).

Hypothesis: the Prostar XL device prevents wound complications in endovascular

aorta repair.

Study objective

The incidence of wound complications in endovascular aneurysm repair (EVAR). VAS scores will be obtained to objectify the advances of a percutaneous approach. Cultures and wound biopsies will be obtained from every patient. Also cost-effectiveness will be studied, in case wound infections could be prevented.

Study design

A randomised non-blinded clinical study with study groups that match perfectly: for one patient needs two groin-incisions during the repair of an aneurysm of the abdominal aorta (AAA). Randomisation consists of passage of the main device of the endoprosthesis. The main device necessitates a larger access (20 french) compared to the contralateral leg (12 french). Exclusion of patients treated with a Nellix-device

Study burden and risks

Patients are required to fill out a VAS score form prior to and 2 weeks after operation.
Cultures of the nose and the perineal region will be obtained during operation. Punch biopsies are taken from the wound, one biopsy is used for culture purposes, and the other biopsy for PA research. The patient will not notice these activities.
In participating centres attention will be paid to the number of surgical site infections in aorta surgery. There is evidence for reduction of surgical site infections, when surgeons pay more attention to wound complications. Possibly the patient will benefit from this investigation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients must be physically and mentally capable of giving consent for randomised femoral access and data storage,
in the possession of an aneurysm of the abdominal aorta with a diameter of at least 55 millimetres (or growth of 5 millimetres or more in half a years* time),
suitable for bifurcated endovascular repair through two femoral access sites, without additional access needed.

Exclusion criteria

Patients with extreme atherosclerosis (more than half (1/2) of the circumference of the CFA)
Previous common femoral artery surgery.
Patients treated with an aorto-monoiliacal device implanted, followed by a femorofemoral cross-over.
Patients in need for more than two femoral accesses (brachial or carotid).
Patients treated with a Nellie device (Endologics)

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2014
Enrollment:	135
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26340
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44578.042.13
OMON	NL-OMON26340

Study results

Date completed:	10-06-2017
Actual enrolment:	137