Differences in wound complications when arterial access is accomplished through puncture of the artery compared to surgical cut down.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26340

Source
Nationaal Trial Register

Brief title
PiERO

Health condition

Percutaneous
Aneurysm
Access
Woundinfection

Sponsors and support

Primary sponsor: University Medical Center of Groningen
Source(s) of monetary or material Support: Abbott Vascular, financial support to appoint a database manager.

Intervention

Outcome measures

Primary outcome

Surgical site infections in the groin; 30 days postoperatively, and during a last control 1 year after operation. Wounds will be evaluated by means of the Southampton Wound Assessment score. When a surgical site infection is diagnosed, a wound-culture should confirm the bacterial contamination

Secondary outcome

wound complications in the groin; till 30 days postoperatively. Evaluated during wound assessment 2 days after surgery, 2 and 6 weeks after surgery.
From all patients a nose-culture and a perineal culture will be obtained. When a surgical site infection occurs, correlation between cultures and SSI's will be drawn; till 30 days postoperatively.
All patients score their wound-comfort in a VAS-score (visual analogue scale): till 6 weeks after surgery.

Study description

Background summary

Background of the study:

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.

Objective of the study:

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).

Study population: 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.

Secundary study parameters/outcome of the study (if applicable): 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable): Patients are required to fill out a VAS score form 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.

Study objective

Minimal invasive puncture of the artery results in less wound complications than surgical cut down

Study design

start inclusion 01-01-2014

interim analysis for safety after inclusion of 50 patients

end inclusion 31-12-2014

end follow up 31-12-2015

Intervention

Randomization between open surgical or percutaneous access in the common femoral artery. One patient with an indication for endovascular repair of an Aneurysm of the Abdominal Aorta (AAA) is operated through arterial access in both groins. One groin in each patient will be operated on in an open surgical manner, and the contralateral side will be operated on in a percutaneous fashion (Prostar/Proglide). Both techniques will be compared in the same patient. Both techniques are similar in operating time.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with an AAA with a diameter of 55 millimeters or growth of 5 millimeters in half a year, suitable for endovascular repair.

Exclusion criteria

history of operations of the common femoral artery.

heavy calcifications in the common femoral artery.

endovascular repair through less than 2 femoral incisions (monoïliacal device) or more than 2 femoral incisions (brachial or carotid)

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	10-11-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41463
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4014
NTR-old	NTR4257
CCMO	NL44578.042.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Register	ID
OMON	NL-OMON41463

Study results

Summary results
N/A