Electrocoagulation or Ligasure for cut down in the groin for exposure of the femoral arteries.

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Relevancy: Groin explorations are regularly performed procedures in vascular surgery. To date, the chosen technique will be either electrocoagulation or the Ligasure, depending on the operator*s preference. It is yet unclear whether the chosen...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON46041

Source
ToetsingOnline

Brief title
DIA-trial

Condition

- Vascular therapeutic procedures

Synonym
lymfleakage, postoperative wound infection, seroma formation, Surgical site infection (SSI)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Seroma formation, Surgical technique, Vascular surgery, Wound infection (SSI)

Outcome measures

Primary outcome

Main study parameter/endpoint: Surgical site infections

Measuring instrument surgical site infection

The Szilagyi classification, classifies surgical site infection from vascular prosthesis based on the depth of the infection. The infection can be assigned to one of three groups: group 1) dermis, group 2) subcutaneous, but not involving the prosthetics and group 3) prosthetics involved in the infection (Szilagyi, Smith, Elliott & Vrandecic, 1972).

As it concerns a vascular surgical population and as prosthetic material may be involved, this classification system will be used additionally in case of an infection (measurement level ordinal).

In order to improve reliability, various instruments will be used to measure postoperative wound infection.

*Surgical site infection of the area operated upon are categorized as follows:

- Superficial postoperative wound infections

- Deep postoperative wound infections

- Organ or anatomical space infections, which organs or anatomical spaces have

been opened or manipulated during the procedure* (National Institute for Health and Environment, 2018, p. 4).

Based on this classification and on the registration instructions of the National Institute for Public Health and the Environment (2018), a measuring instrument has been developed for surgical site infection that can be used by the researchers during the measurement moments (measurement level ordinal).

As wound management policy is not included in the results, wound management policy is standardized on the basis of wound care guidelines (Nederlandse Vereniging voor Heelkunde, 2013), literature on surgical and traumatic wounds by Groetelaers & Van Ruitenberg (2015) and the WCS classification model to secure the reliability and validity of the research (the same researcher signature). The WCS classification model is a tool to determine the local wound management objectives and to determine the correct wound management product (Vermeulen, Schreuder, Lubbers & Ubbink, 2005). Wound management policy is incorporated in the surgical site infection measuring instrument.

Secondary outcome

Secondary study parameter/endpoint: Pain and quality of life.

Measuring instrument quality of life EQ-5D-3L

Quality of life can be measured using the EuroQol Group's measuring instrument EQ-5D. This is a standardized measuring instrument applicable in various health conditions and treatments. It is used, inter alia, in clinical trials. The effects of treatment can thus be evaluated. In addition, longitudinal data

collected with the EQ-5D can be used on an individual level to monitor the patient's health status over time. (Szende, Janssen & Cabases, 2014). The EQ-5D-3L version was introduced by the EuroQol group in 1990. It consists of two parts. First, the patient is invited to score five levels of health, being the health status of mobility, self-care, daily activities, pain/discomfort and anxiety/depression. Per health status, the patient chooses one out of three possible answers (measurement level nominal and ordinal). Next is the visual analogue scale (EQ VAS). Here, the patient can indicate how well or badly his or her current health is experienced. The measuring scale ranges from 0 to 100, with 100 representing the best health level imaginable to the patient. The EQ VAS is used as a quantitative measuring instrument (measurement level ratio). The patient is intended to fill out the measuring instrument him/herself within a few minutes. EuroQol is complementary to other measuring instruments regarding quality of life. Various studies have shown that the EQ-5D-3L is a reliable and valid measuring instrument, capable of measuring quality of life in a reproducible manner. (Brooks, 1996). Age, gender and educational attainment are included as variables in the measuring instrument EQ-5D-3L.

Measuring instrument with regard to pain

The most frequently mentioned definition of pain stems from the International Association for the Study of Pain (IASP, 1994): *An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage*. Pain is always subjective and consequently every individual uses the word pain in relation to a previous experience with

an injury (Kumar & Elavarasi, 2016). Pain scoring systems have been developed since the beginning of the last century. At first they were only used as research instruments but over the last few decades increasingly as a clinical parameter for monitoring and evaluating postoperative pain management.
To assess pain, the intensity of the pain can be measured by means of a Numerical Rating Scale (NRS), one of the most widely used clinical methods (Hartrick, Kovan & Shapiro, 2003). This is an aspecific measuring scale consisting of eleven numbers ranging from zero to ten. Zero meaning no pain and ten the most pain imaginable. The patient indicates the severity of his/her pain by circling a number, which takes about a minute to complete. Since some concentration, coordination and understanding of numbers is required, the NRS is suitable for children from the age of eight onward (Von Baeyer, 2006) and for elderly not cognitively impaired. (Ware, Epps, Herr & Packerd, 2006). In recent research, Karcioglu, Topacoglu, Dikme and Dikme (2018) conclude that the NRS is a valid, reliable, suitable and clinically usable measuring instrument.
In the Netherlands, the NRS is applied in accordance with the guidelines of the handbook of VMSzorg (2009), which contains a standardized scheme for pain measurement.
The NRS is used as an ordinal measuring instrument.

Study description

Background summary

There are various vascular surgeries in which artery exposure through the groin (groin exploration) is necessary. Wound infections are relatively common in

groin explorations. Wound infection and lymphatic problems account for the majority of wound complications in the groin (Ploeg, Lardenoye, Vrancken Peeters, Hamming & Breslau, 2009). The surgical technique, including the degree of tissue damage, the size of the wound bed, the use of foreign materials, drains and the manner in which the surgery has been performed, are factors that contribute to the development of SSIs (Infection Prevention Working Group, 2011).
In February 2019, a randomized control trial will start in the University Medical Center of Groningen and Ommelander Hospital Groningen focusing on two common surgical methods in vascular surgical operations, including groin explorations. The methods differ in the use of techniques, being either electrocoagulation or the Ligasure. Both these techniques are used to burn and cut away tissue to reach the artery. Small blood vessels are cauterized. These techniques differ in that the Ligasure has a constant pressure and intelligent energy release (closed loop system). Tissue layers merge through the automatic sealing process (Medtronic, 2018). The Ligasure indicates the completion of the burn and by the electrocoagulation this is up to the vascular surgeon him/herself.

Hypothesis
Applying the Ligasure in groin explorations will result in fewer postoperative wound infections and seroma formation in comparison to the use of the standard groin exploration using electrocoagulation, resulting in less pain and an improved quality of life.

Study objective

Relevancy:
Groin explorations are regularly performed procedures in vascular surgery. To date, the chosen technique will be either electrocoagulation or the Ligasure, depending on the operator*s preference. It is yet unclear whether the chosen technique has any influence on the occurrence of a SSI or seroma formation.

The research aim is to determine whether applying the Ligasure will lead to a reduction of postoperative wound infections or seroma formation and thereby will contribute to an improvement of quality of life and a reduction of pain in comparison to the diathermy. The results of this research will elucidate whether the Ligasure should be applied as the standard technique in groin exploration.

Study design

This is a comparative, quantitative, longitudinal prospective study (double-blind randomized controlled trial). Experimental, randomized, double-blinded (for patients and nurse practitioner).

Intervention

The use of Ligasure for cut down in the groin for exposure of the femoral arteries

Study burden and risks

Care as usual. There are no other potential risks or benefits than normally associated with the surgery (postoperative wound infection and seroma formation).

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 undergoing an inguinal approach of the femoral arteries.
Patients older than 18 years and competent.
Patients have to be able to comprehend the patient information. Filling out, signing and returning of the informed consent form.

Exclusion criteria

The use of mono-polair coagulation is contra-indicated
Patients not giving informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Ligasure
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-02-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-05-2021
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

No registrations found.

In other registers

Register	ID
CCMO	NL66083.042.18

Study results

Date completed: 01-01-2022

Summary results
Trial never started