

A randomised comparison of the complications, patient- and nursing experiences between the Buttonhole- and the Rope-ladder/area cannulation techniques in hemodialysis arteriovenous fistulas

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This study will compare the buttonhole cannulation technique and the rope-ladder/area technique. Primary the number of complications will be compared. Secondary the differences between both techniques in patient experience and cannulation ease for...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON35466

Source

ToetsingOnline

Brief title

A comparison of the Buttonhole and Rope-ladder/area cannulation techniques

Condition

- Other condition
- Nephropathies

Synonym

n.v.t.

Health condition

Vasculair

Research involving

Human

Sponsors and support

Primary sponsor: Scheper Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Buttonhole, Complications, Dialysis, Needle insertion

Outcome measures

Primary outcome

Primary outcome of this study will be the independent differences of complications between the buttonhole cannulation technique and the rope-ladder/area cannulation technique. The following parameters will be observed: development of aneurysms, occlusions and number of shunt infections.

Secondary outcome

Secondary parameters in this study are patient experience and nursing experience in cannulation ease. The patient experience will be monitored with VAS scores for pain and cannulation fair. The nursing experience will be based on the number of attempts to cannulate, the use of ultrasound during cannulation, the time it takes to cannulate a single patient and the sort of needle the use.

Adjacent to this the differences of development of haematoma, number of interventions and re-bleeding between the buttonhole cannulation technique and

the rope-ladder/area technique will be scored.

Study description

Background summary

For the optimal treatment of haemodialysis patients is essential to acquire and maintain an adequate vascular access. Preferably patients get an arteriovenous fistula, which will be cannulated every dialysis session. For cannulation of a fistula exist three commonly used techniques: the rope-ladder technique, the area technique and the buttonhole technique. The rope-ladder technique uses the complete fistula. Every session, the new puncture place is chosen below the last puncture place, so the puncture places will be equally divided over the total fistula. In the area technique every consecutive puncture will be placed arbitrary in a region on the fistula. In practice the rope-ladder as well as the area technique are used simultaneously with the same patient. An other option to cannulate a fistula is the buttonhole technique. This technique cannulates every time on the same spot, in the same angle and depth. After a few cannulations there will be formed a tunnel of scar tissue from the skin to the blood vessel. After the dialysis session the tunnel closes with a flap of the vessel wall and a scrub on the skin.

Different publications suggest that the patients who are dialysing with the buttonhole cannulation technique develop less complications, is more patient-friendly and is easier for the nurses in comparison to the rope-ladder/area technique. Both techniques are commonly used, but real scientific evidence is still missing to conclude: one technique is superior to the other technique. The main objective of this study is to compare the buttonhole cannulation technique with the rope-ladder/area technique. The primary outcome will be the number of complications.

Study objective

This study will compare the buttonhole cannulation technique and the rope-ladder/area technique. Primary the number of complications will be compared. Secondary the differences between both techniques in patient experience and cannulation ease for the nurses will be observed.

Study design

This will be a randomised cohort study.

Study burden and risks

To the buttonhole cannulation technique apply the same risks to complications

as the rope-ladder/area technique. These are: chance of vascular occlusion, haematoma, aneurysm development and infections. Many different publications suggest that the patients who are dialysing with the buttonhole cannulation technique develop less complications, is more patient-friendly and is easier for the nurses in comparison to the rope-ladder/area technique. Some minor publications suggest that the buttonhole cannulation technique is a risk factor to develop shunt infection. But existing literature about the phenomenon is scarce; further research will be needed to prove a connection. The participation in this study won't take extra time of the participant.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Arteriovenous fistula, bloodflow of at least 600ml/min, vessel diameter > 6mm, possibility to

4 - A randomised comparison of the complications, patient- and nursing experiences b ... 25-05-2025

use two needles during dialysis.

Exclusion criteria

Legal incapacity, unable to speak Dutch, known vasculair occlusions and/or aneurysm, already use of a buttonhole.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 23-02-2012

Enrollment: 60

Type: Actual

Ethics review

Approved WMO

Date: 22-12-2011

Application type: First submission

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	NL38073.042.11