Creation of buttonhole cannulation tracks: conventional vs supercath

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Compare succesfull creation and usage of the buttonhole track for hemodialyses, created by either the conventional way or with the supercath

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON35942

Source
ToetsingOnline

Brief title
Buttonhole cannulation tracks: conventional vs supercath

Condition

- Renal disorders (excl nephropathies)
- Vascular therapeutic procedures

Synonym
hemodialysis -dialysis

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: ziekenhuis

Intervention

Keyword: buttonhole, hemodialysis, supercath

Outcome measures

Primary outcome

Compare the effect of buttonhole track creation by either the conventional or

the supercath method on

- succesfull creation buttonhole after development phase (supercath 10 days-

traditional 12 days)

- succesfull usage buttonhole track during 6 months (scoring number

miscannulations)

Secondary outcome

Compare the effect of buttonhole track creation by either the conventional or

the supercath method on

- skin/shunt infections

- pain perception patient (VAS scores)

- costeffectiveness/ logistics

- required angiografpic inrteventions.

Study description

Background summary

An easy accesable av fistula is an essential requirement for hemodialysis. Unfortunately, frequently there are cannulation problems due to difficult accessability which results in increased regional cannulation, pain, miscannulation and fear for many hemodialysis patients. By using a buttonhole, i.e. a fistula between the skin and the vascular access, most of these problems disappear. By using a new creation method for the buttonhole with the

supercath , the buttonhole can be created with more ease and in a better way due to less variation in comparison to the conventional buttonhole.

Study objective

Compare succesfull creation and usage of the buttonhole track for hemodialyses, created by either the conventional way or with the supercath

Study design

Randomised open intervention study

Intervention

creation buttonhole track by either the conventional or the supercath method.

Study burden and risks

Time consumption:
-During followup the patient is requested to do VAS scoring lists in total 9 times in 6 months, requiring 5 min-session. This can be done duing the hemodialysis sesion

-Risks:
The buttonhole creation by the conventional method is known to be associated with an increased risk for infection during the creation phase in comparison to regular cannulation without a buttonhole due to the usage of foreign material i.e. biohole plugs, which are applied after each dialysis session and removed before the next session. This risk may be higher by using the supercath needles because these needles remain in situ for 10 days, while used for dialysis and the creation of the buttonhole cannulation track. Earlier research did not observe an increased risk for infection with this method. However,to prevent infection, this researchprotocol uses mupirocin cream applied to the exit side.
Also there is a very small risk of disconnection of the supercath needle. In order to prevent this the needle is fixated by sterile plasters. In case this occurs the patient should act as if it was a regular shuntbleeding. Because of this small risks the exclusion criteria for this study encompass incapability to press the fistula and living alone.

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

-patient receiving hemodialysis
-recently created AV fistula or existing AV fistula with cannulation problems

Exclusion criteria

-PTFE loop
-shunt depth> 0,8 cm
-physical inability to create pressure on AV fistula during shunt bleeding
-living alone

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Supercath CLS 502
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-07-2011
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL36294.101.11