Prevention of local thromboembolic complications during continuous infusion of coagulation factor concentrates: parallel infusion of saline versus heparin and parallel infusion of saline?

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To demonstrate that parallel infusion of saline added to the continous infusion of clotting factor concentrates prevents local thromboembolic complications to the same extent as heparin together with a parallel infusion of saline does.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Blood and lymphatic system disorders congenital
Study type	Interventional

Summary

ID

NL-OMON36776

Source
ToetsingOnline

Brief title
Continuous infusion of factor concentrate: with or without heparin?

Condition

- Blood and lymphatic system disorders congenital

Synonym
bleeding disorder, Haemophilia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Coagulation factor concentrates, Continuous infusion, Heparin, Saline

Outcome measures

Primary outcome

Lifespan of the intravenous catheters in both groups.

Secondary outcome

V.I.P. score, a standardised score for thrombophlebitis.

Study description

Background summary

At the time of introduction of continuous infusion of clotting factor concentrates, thrombophlebitis was a frequently seen complication. In the 90's a small amount of heparin was experimentally added to the clotting factor concentrates during continous infusion in order to prevent thrombophlebitis and some centres have been using this method ever since. Recent developments in the field of clotting factor concentrates have led to the improvement of these products. Moreover, worldwide there are different methods in use to prevent thrombophlebitis, such as parallel infusion of saline. No comparative studies on this topic have been performed to define the best prophylactic regimen and the current prophylactic treatment of thrombophlebitis is therefore not evidence based. Because adding heparin is not free of risks, parallel infusion of saline has the potential of being safer. In this trial we want to evaluate the efficacy of a parallel infusion of saline compared to heparin in the prevention of local thromboembolic complications in patients treated with continuous infusion of clotting factor concentrates.

Study objective

To demonstrate that parallel infusion of saline added to the continous infusion of clotting factor concentrates prevents local thromboembolic complications to

the same extent as heparin together with a parallel infusion of saline does.

Study design

An open label randomised trial.

Intervention

Two interventions will be compared. In the first group the intervention consists of adding heparin, next to a parallel infusion of saline, to the clotting factor concentrates during continous infusion. In the second group the intervention consists of parallel infusion of saline to the continuous infusion of clotting factor concentrates.

Study burden and risks

It is not expected that the group of patients who will receive a parallel infusion of saline have a higher risk for developing thrombophlebitis than the group of patients who will receive heparin. There is very low risk with regard to serious complications.
However, there is a possibility that if the patient needs extra intravenous saline according to the treating physician, a second entry must be placed for intravenous infusion.

This trial will contribute to an evidence-based protocol for prophylactic treatment for local thromboembolic complications seen in continuous infusion of clotting factor concentrates. Possibly this can lead to safer treatment regime.

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 with haemophilia A
- Planned for elective operation
- Getting a continuous infusion of coagulation factor concentrates (FVIII)
- 18 years and older

Exclusion criteria

Under 18 years
The use of FVIIa (used by patients with inhibitors)

Study design

Design

Study type:	Interventional
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):	16-08-2011
Enrollment:	42
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Heparin-sodium
Generic name:	heparin-sodium 100 IU / ml
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	02-10-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-08-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-02-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-04-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-05-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2009-012091-26-NL
CCMO	NL27872.041.09