Nadroparine tijdens nachtelijke hemodialyse

No registrations found.

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

Summary

ID

NL-OMON24636

Source
NTR

Brief title
N/A

Health condition

accumulation of Nadroparine during hemodialysis

Sponsors and support

Primary sponsor: Stichting wetenschap Internegeneeskunde & MDL, Medisch Centrum Leeuwarden.
Source(s) of monetary or material Support: Stichting wetenschap Internegeneeskunde & MDL, Medisch Centrum Leeuwarden.

Intervention

Outcome measures

Primary outcome

Anti-Xa activity (IU/ml) before and after the first and last dialysis of the week to determine if accumulation occurs.

Secondary outcome

-Bloodflow during dialysis

-Flow of dialysis fluids

-Renal function

-Kt-V

-Bleeding events

-Clotting in the dialysis filter

Study description

Background summary

Patients undergoing nocturnal hemodialysis are being administered an extra dosage of nadroparine compared to conventional hemodialysis. Nadroparine prevents clotting in the extra corporeal system. The currently used dosage regime is based on experience and international guidelines. There is no scientific evidence for this regime. It is unknown if nadroparine accumulates using a dosage of nadroparine wich is twice as high in a week compared to conventional hemodialysis. In theorie this could lead to a higher bleeding risk. This studie is designed to establish if and when accumulation occurs and to establish if the anti-Xa concentration measured are associated with a higher risk of bleeding events.

Study objective

Nadroparine accumulates at higher dosage regimes in patient ondergoing nocturnal hemodialysis

Study design

Blood is taken 4 times. Before and after the first hemodialysis of the week and before and after the last hemodialysis of the week.

Intervention

The use of 4 bloodsamples taken from the dialysisline to determine anti-Xa activity (IU/ml)

Contacts

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Eligibility criteria

Inclusion criteria

Patients (18

Exclusion criteria

- The use of other drugs wich block factor-Xa other than nadroparine. This includes dabigatran, apixaban, rivaroxaban, LMWH’s, heparine and fondaparinux.

- The use of Cofact or Beriplex during measurements

- Alteration in the dosage regime of anticoagulantia

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2013
Enrollment:	14
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-09-2013
Application type:	First submission

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
NTR-new	NL4011
NTR-old	NTR4183
Other	Regionale toetsingscommissie patientgebonden onderzoek (RTPO), Medisch Centrum Leeuwarden : RTPO 900
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A