Anti-Xa activity of nadroparin after a dose reduction (XANDO)

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23816

Bron
NTR

Verkorte titel
XANDO

Aandoening

Renal impairment
Venous thromboembolism
Nierinsufficiëntie
Veneuze trombo-embolie

Ondersteuning

Primaire sponsor: Medisch Centrum Leeuwarden
Overige ondersteuning: Medisch Centrum Leeuwarden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The mean anti-Xa activity in patients with an eGFR < 60 ml/min and patients with an eGFR > 60 ml/min treated with therapeutic doses of nadroparin.

Toelichting onderzoek

Doel van het onderzoek

Low-molecular-weight heparins (LMWHs) are frequently used in the prophylaxis and therapy of venous thromboembolism (VTE) and the prophylaxis of arterial thromboembolism. LMWHs are mainly excreted by the kidneys and may accumulate in patients with renal impairment, leading to an increased anti-Xa activity which is associated with an increased risk of bleeding complications. Current dosage guidelines of the Dutch Federation of Nephrology (NfN) and the Royal Dutch Pharmacists Association (KNMP) recommend a dose reduction in patients with renal impairment, followed by determination of the anti-Xa activity in patients treated for more than three days. The evidence supporting this recommendation is sparse. To date, no data is available about the effect of nadroparin in obtaining an adequate anti-Xa activity in patients with renal impairment (eGFR < 60 ml/min) after dose reduction, but also not in patients with a normal renal function (eGFR > 60 ml/min) treated with a standard therapeutic dose of nadroparin. In this study, we therefore determine the anti-Xa activity after a reduced therapeutic dose of nadroparin in patients with an eGFR < 60 ml/min in comparison with the anti-Xa activity after a standard therapeutic dose of nadroparin in patients with an eGFR > 60 m/min, using the dosage guideline of the Dutch Federation of Nephrology

Onderzoeksopzet

A blood sample will be drawn by venipuncture 4 hours after the 6th administration of Fraxiparine or the 3rd administration of Fraxodi. Though, blood samples collected 4 hours after the 7th respectively 4th administration are also accepted.

Onderzoeksproduct en/of interventie

One venous blood sample

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age at least 18 years
- Therapeutic dose of Fraxiparine or Fraxodi
- Subcutaneous nadroparin administration for at least three days
- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Use of nadroparin before hospital admission
- Patients known for heparin resistance
- Patients on hemodialysis
- Use of antifactor Xa inhibitors other than nadroparin (all remaining LMWHs, dabigatran, apixaban, rivaroxaban, heparin and fondaparinux) within 7 days before the start of the study or during the study
- Use of Cofact or Beriplex within 7 days before the start or during the study

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	194
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	20-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4704
NTR-old	NTR4974
Ander register	NL50430.099.14 : XANDO

Resultaten