Evaluation of the time dependent variability of the anti-factor Xa activity of therapeutic nadroparin in critically ill patients: a pharmacokinetic study

No registrations found.

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

Summary

ID

NL-OMON20466

Source
Nationaal Trial Register

Brief title
VARIAXA

Health condition

Critically ill patients

Sponsors and support

Primary sponsor: Martini Ziekenhuis, Groningen
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The incidence of inadequate estimated peak anti-factor-Xa levels after therapeutic

nadroparin in a general intensive care unit population

Secondary outcome

To evaluate the pharmacokinetics of therapeutic nadroparin in a general intensive care unit population by measuring anti-factor Xa levels.

Study description

Background summary

Monitoring the peak anti-factor-Xa is advised in the treatment of therapeutic nadroparin in cases of less predictable pharmacokinetic properties such as renal insufficiency, obese patients and pregnant woman. Target ranges of this peak anti-factor-Xa are measured 3 to 5 hours after the s.c. injection of nadroparin. Based on the literature the time to reach the peak anti-factor-Xa of nadroparin (t-max) can be expected also before and after this 3 to 5 hour time-window. Critically ill patients experience divers physiological changes and may use medication that can significantly affect the pharmacokinetics of subcutaneous administered nadroparin. Although the impact of this variable t-max on the height of the measured anti-factor-Xa is not known, the measured levels are clinically used for dosage adjustments of the nadroparin in the treatment of venous thromboembolism and prevention of stroke in atrial fibrillation. In this study we will investigate the reliability of the 3 - 5 hour sampling-window of anti-Xa for changing dosages of therapeutic nadroparin in critically ill patients.

Study objective

We hypothesize that in critically ill patients, measuring the anti-factor-Xa randomly in a 3 to 5 hours timeframe, may introduce a significant variation in the measured anti-factor-Xa and can seriously underestimate the real peak anti-factor-Xa.

Study design

Measurements will take place up to 12 hours after a 2-daily administration and 24 hours after a 1-daily administration of nadroparin.

Intervention

NA

Contacts

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Eligibility criteria

Inclusion criteria

(1) Admitted to the Intensive Care with nadroparin in therapeutic dose (1-daily or 2-daily)
(2) Age ≥ 18 years

Exclusion criteria

(1) Pregnancy
(2) Requiring hemodialysis (HD) or Continuous Veno-Venous Hemofiltration (CVVH)
(3) Treated with a DOAC, unfractionated heparin, another LMWH, or a GP IIb / IIIa receptor antagonist 72hours to 0 hours before the first bloodsample is drawn or during bloodsampling.
(4) Participation in another study

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:	Recruiting
Start date (anticipated):	23-07-2020
Enrollment:	25
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-11-2019
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	NL8205
Other	Regionale Toetsingscommissie Patiëntgebonden Onderzoek : RTPO 1088

Study results