Prospective study into the relation between bodyweight en the effect of thrombosis prophylaxis in patients admitted to hospital

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Embolism and thrombosis
Study type	Observational non invasive

Summary

ID

NL-OMON48903

Source
ToetsingOnline

Brief title
PRIORITY

Condition

- Embolism and thrombosis

Synonym
deep vein thrombosis, venous thromboembolism

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht

Source(s) of monetary or material Support: Stichting Cornelis Visser

Intervention

Keyword: Anti-Xa levels, Bodyweight, Kidney function, Thrombosis prophylaxis

Outcome measures

Primary outcome

Determinants:

1. Body weight will be expressed as lean body weight (measured with an impedance-measurement), BMI and the absolute body weight in kilograms. This will be analyzed continously as well as in categories of <50kg; 50-100kg; and >100kg.

2. Kidney function will be expressed as the creatinine clearance in ml/min/1.73m2 calculated with the CKD-EPI en Cockcroft and Gault formulas.

Primaire outcome:

Anti-Xa levels 4 hours after administration of a standard prophylactic dose of nadroparin 2850 IE .

Secondary outcome

1. Anti-Xa levels <0.2 IU/ml or >0.5 IU/ml (=outside prophylactic range).

2. Anti-Xa levels 4 days after administration of the standard nadroparin dose of 2850 IE in 4 subgroups i.e. bodyweight<50kg; >150kg; creatinine clearance 30-60 ml/min/1.73m2; and <30 ml/min/1.73m2.

3. Any occurence of deep venous thrombosis, pumonary embolism or bleeding

within 8 weeks after nadroparine 2850 IE administration.

Study description

Background summary

Prophylatic low-molecular-weight heparin (LMWH) is effective in preventing venous tromboembolism in patients with high risk, such as patients admitted to a hospital. Furthermore, the effectivity of therapeutic LMWH is reduced in overweight patients or patients with reduced kidney function. However, it is not known whether this is also the case for the effectivity of prophylactic LMWH.

Study objective

The objective of the study is to evaluate in a prospective setting the effect of body weight on anti-Xa levels in the blood after administration of prophylactic nadroparin 2850 IE to patients admitted to the hospital. Second, we want to see what the effect is of kidney function on anti-Xa levels.

Study design

Prospective study, in which we will measure anti-Xa levels in 220 patienten admitted to the hospital that have an indication for thrombosis prophylaxis with nadroparine 2850 IE. Anti-Xa levels will be measured 4 hours after administration of the nadroparin. Furthermore, in all patients body weight, body-mass index, lean-body mass andkidney function will be measured. Finally we will contact the patients by mail to ask whether a VTE or bleeding event has occurred.

Study burden and risks

The treatment is standard procedure that will not contain any additional risk for the study participants.
The burden concerns approximately 30 minutes of time, additional measurements including and impedance measurement and an extra blood withdrawal of 3 mL. For the second secondary study outcome, 4 subgroups of patients will be identified in whom we will do a second anti-Xa level measurement 4 days after the first (in case a patient is still admitted). This will require another blood withdrawal of 3 mL.

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

admission to the hospital for at least 1 night
indication for nadroparine 2850 IE prophylaxis
age > 18 years
signed informed consent

Exclusion criteria

presence of deep venous thrombosis or pulmonary embolism
use of Vitamin K antagonist or DOAC
trombocytes < 50 10*9/L

any other contra-indication for nadroparine 2850 IE

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2018
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-08-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29346
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65998.100.18
OMON	NL-OMON29346