Prospective, pharmacokinetic study for determination of the relationship between lean body weight and anti-Xa activity 4 hours after subcutaneous administration of 5700 IU nadroparin in morbidly obese patients after bariatric surgery.

Published: 03-07-2012
Last updated: 26-04-2024

Primary objective: prospective evaluation of the relationship between lean body weight and anti-Xa activity of 5700 IU nadroparin 4 hours after subcutaneous administration in morbidly obese patients.Secundary objectives: - Correlation between other…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37098

Source
ToetsingOnline

Brief title
Nadroparin and anti-Xa activity after bariatric surgery

Condition

- Other condition

Synonym
morbid obesity, profylaxis thrombosis

Health condition

antistolling profylaxe bij bariatrische chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: eigen financiering;geen externe bron

Intervention

Keyword: Anti-Xa activity, Bariatric surgery, Morbid obesity, Nadroparin

Outcome measures

Primary outcome

anti-Xa activity 4 hours after subcutaneous administration of 5700 IU

nadroparin

Secondary outcome

dosage linearity of nadroparin (between 2850 IU and nadrparin 5700 IU)

Study description

Background summary

Morbidly obesity is an increasing problem in the Western countries in the last 10 years. Morbidly obese patients have increased risk for venous thrombotic events (VTE), such as pulmonary embolism (PE) and deep venous thrombosis (VTE). In addition, bariatric surgery has also increased risk for thromboembolic complications, with significant risk for morbidity and mortality. Low molecular heparin as perioperative atithromobotic prophylaxis is common practice, however, there is a lack of evidence for the dosage of nadroparin. According to smaller cohort studies, higher prophylactic dosage of nadroparin (5700 IU) is needed in morbidly obese patients.
Plasma levels of nadroparin, and indirectly the effect of nadroparin, can be measured by determination of anti-Xa activity. Prophylactic range of anti-Xa activity is 0.2 - 0.5IU/ml 4 hours after administration of nadroparin. In

non-obese patients 2850 IE nadroparin is an adequate dosage to reach this range. In morbidly obese patients, these dosage is unknown. Recent study showed a linear relationship between lean body weight and 5700 IU nadroparin in morbidly obese patients.

Study objective

Primary objective: prospective evaluation of the relationship between lean body weight and anti-Xa activity of 5700 IU nadroparin 4 hours after subcutaneous administration in morbidly obese patients.

Secundary objectives: - Correlation between other body sizes (such as BMI/ total body weight) and renal function (GFR) and anti-Xa activity of 5700 IU nadroparin 4 hours after subcutaneous administration after bariatric surgery.

- Determination of dosage linearity of anti-Xa activity of nadroparin

Study design

prospective, obeservational (with invasive measurements), pharmacokinetic study

Study burden and risks

Because the obeservational nature of the study, there is no directly benefit for participation of the study. The aim of the study is to optimilize perioperative antithrombotic profylaxis after bariatric surgery in morbidly obese patients. Extraprotocolar, the participants will be administered for 3 days nadroparine 2850 IU. Because this short term, the risks are negligible.

Contacts

Public
Rijnstate Ziekenhuis

Wagnerlaan 55
6800 TA Arnhem
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
6800 TA Arnhem
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

approval for Roux-en-Y gastric bypass
body weight of > 140 kg

Exclusion criteria

renal impairment (GFR < 30 and/or serum creatinin > 150)
Anticoagulation disorders (PT/APT > 2x norm)
Use of oral anticoagulation (such as acenocoumarol)
pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Fraxiparine
Generic name:	Nadroparin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-07-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-10-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2012-002816-19-NL
CCMO	NL41144.091.12