The effect of body weight on trough concentrations of DOACs in patients.

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The aim of this study is to investigate the effect of body weight on the trough concentrations of DOACs. Eliquis®, Xarelto®, Lixiana® and Pradaxa®

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

Summary

ID

NL-OMON46689

Source
ToetsingOnline

Brief title
BC_DOAC

Condition

- Other condition

Synonym
trough concentration/ concentration prior to next dose

Health condition

TDM

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: eigen middelen (opleidingsgeld)

Intervention

Keyword: body weight, DOAC, trough concentration

Outcome measures

Primary outcome

The main study parameter is body weight and the primary endpoint is the DOAC

trough concentration.

Secondary outcome

The secondary endpoints will be

- The trough anti-FXa activity (apixaban, rivaroxaban and edoxaban)

- The trough anti-FIIa activity (dabigatran)

Study description

Background summary

This study will reveal more information about DOAC drug concentrations related to body weight. Edoxaban and apixaban dose recommendations are made for low body weight as described in the SPC. The SPCs of dabigatran and rivaroxaban describe to use the medicines with caution when the patient*s body weight is less than 50 kg for rivaroxaban and less than 60 kg for dabigatran, especially when combined with other oral anticoagulants. Using with caution is hard to define in daily practice, so a clear advice is required. This also applies for people with a high bodyweight where almost all SPCs, except edoxaban, claim that DOAC exposure is lower for this patient group. Any new information about the relation body weight and DOAC drug concentrations can provide new insights on how to treat these patients with under* and overweight in a safe and effective way.

Study objective

The aim of this study is to investigate the effect of body weight on the trough concentrations of DOACs. Eliquis®, Xarelto®, Lixiana® and Pradaxa®

Study design

This exploratory cohort study will investigate the effect of body weight on the trough concentrations of DOACs in patients from the Haga Teaching Hospital.

Study burden and risks

The risks the patients are exposed to are complications from blood sampling.

Contacts

Public
HagaZiekenhuis

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Scientific
HagaZiekenhuis

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Male or female * 18 years
- Treated with a DOAC (rivaroxaban, dabigatran, apixaban, edoxaban) in a therapeutic or prophylactic dosage for at least five days

- eGFR > 50 ml/min
- Is not mentally disabled
- Good understanding of the Dutch language
- Written informed consent

Exclusion criteria

- Collected blood sample is not a trough concentration
- Relevant co-medication (table 1 of study-protocol)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2018
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Eliquis
Generic name:	Apixaban
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Lixiana
Generic name:	Edoxaban
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Pradaxa
Generic name:	Dabigatran
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xarelto
Generic name:	Rivaroxaban
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-09-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-12-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-08-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-09-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-12-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2017-003569-91-NL
CCMO	NL62896.098.17

Study results

Date completed:	23-01-2019
Actual enrolment:	167