The effect of body weight on the medicine concentrations of dabigatran, edoxaban, apixaban and rivaroxaban in blood.

No registrations found.

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

Summary

ID

NL-OMON22392

Source
NTR

Brief title
BC_DOAC study

Health condition

DOAC, body weight, trough concentration
DOAC, lichaamsgewicht, dalspiegel

Sponsors and support

Primary sponsor: Haga Teaching Hospital and
Central Hospital Pharmacy The Hague
Source(s) of monetary or material Support: Self funding

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to investigate the effect of body weight on the trough concentrations of DOACs.

Secondary outcome

- To investigate the effect of body weight on anti-Factor Xa (FXa) activity for apixaban, rivaroxaban and edoxaban.

- To investigate the effect of body weight on anti-Factor IIa (FIIa) activity for dabigatran.

Study description

Background summary

Rationale:

High trough concentrations of direct oral anticoagulants (DOACs) are related to a higher bleeding risk while low trough concentrations increase the risk of an ischemic stroke / systemic embolic event (SEE) risk. Different factors, including body weight, may have an impact on the plasma concentrations of DOACs. Dose reductions for the DOAC edoxaban are recommended for patients with a body weight of less than 60 kg and for apixaban when patients with atrial fibrillation have two or more of the following critiria: body weight less than 60 kg, serum creatine > 133 umol/L or age > 80 year. This is in contrast with the other DOACs where no dose adjustments based on body weight are recommended. It seems that there is need for further research for all DOACs to investigate if dose adjustment is recommended for patients with low or high body weight.

Objective: To investigate the effect of body weight on the trough concentrations of DOACs in patients.

Study design:

Exploratory cohort study.

Study population:

Patients (¡Ý 18 year) treated at the in- or outpatient clinic of the Haga Teaching Hospital who are prescribed a DOAC (rivaroxaban, dabigatran, apixaban or edoxaban).

Main study parameters/endpoints: The main study parameter is body weight and the primary endpoint is the DOAC trough concentration.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients using DOACs as their standard care can participate in this study. The study will take place according to the Dutch Medical Research Involving Human Subjects Act (WMO) as patients are asked to provide a one-time blood sample. Patients have to provide a written informed consent before entering the study. After providing the written informed consent a medication reconciliation interview will take place. Blood sampling for the study will be combined, if possible, with normal care so that the need for extra venepunctures will be minimalized. The risks that patients are exposed to are complications from blood sampling. To reduce complications, sampling procedures will be performed by health care professionals who are trained in these procedures.

Study objective

Body weight has an effect at the trough concentrations of DOACs in patients.

Study design

The inclusion will take place from February 2018 till February 2019 in the Haga Teaching Hospital. Blood samples will be analysed by the department of clinical chemistry LabWest for anti-FXa activity or anti-FIIa activity and renal function. The trough concentration of the DOAC will be analysed by the Central Hospital Pharmacy (AHZ) laboratory.

Intervention

Patients will only use the licensed DOACs (Eliquis®, Xarelto® Lixiana® and Pradaxa®) as standard care prescribed by their physician. No intervention will take place, only DOAC trough concentrations will be measured in patients. For this reason patients have to provide a one-time blood sample.

Contacts

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Eligibility criteria

Inclusion criteria

- Male or female ≥ 18 years

- Treated with a DOAC (rivaroxaban, dabigatran, apixaban, edoxaban) in a therapeutic or prophylactic dosage for at least 5 days

- eGFR > 50 ml/min

- Is not mentally disabled

- Good understanding of the Dutch language

- Written informed consent

Exclusion criteria

- The use of relevant co-medication: Ketoconazole, Posaconazole, Voricanazole , Itraconazole , Fluconazole, HIV protease inhibitors, Ticagrelor , Verapamil , Diltiazem (except dabigatran) , Amiodarone , Quinidine, Cyclosporin, Tacrolimus, Clarithromycin, Erythromycin, Carbamazepine, Rifampicin, St John¡¯s wort, Phenytoin
phenobarbital

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-02-2018

Enrollment:	160
Type:	Unknown

Ethics review

Positive opinion Date:	31-01-2018
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	NL6803
NTR-old	NTR6989
Other	MEC : 17-120

Study results

Summary results
N/A