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

Gepubliceerd: 31-01-2018 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22392

Bron
NTR

Verkorte titel
BC_DOAC study

Aandoening

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

Ondersteuning

Primaire sponsor: Haga Teaching Hospital and Central Hospital Pharmacy The Hague
Overige ondersteuning: Self funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Haga Teaching Hospital, Central Hospital Pharmacy The Hague, The Netherlands

J.M. Borst
Den Haag
The Netherlands

Wetenschappelijk

Haga Teaching Hospital, Central Hospital Pharmacy The Hague, The Netherlands

J.M. Borst
Den Haag
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	160
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	31-01-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6803
NTR-old	NTR6989
Ander register	MEC : 17-120

Resultaten

Samenvatting resultaten
N/A