Hartritmestoornissen (QT-verlenging op het ECG) door domperidon

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28199

Bron
Nationaal Trial Register

Verkorte titel
QT-DOM

Aandoening

QT-prolongation, cardiac dysrythmias

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Application is under consideration.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

QT-time on ECG performed 30-60 minutes after the fourth dosage of domperidone.

Toelichting onderzoek

Achtergrond van het onderzoek

In literature, domperidone has been linked to QT-prolongation resulting in acute cardial dysrythmias and sudden death. However, in practice doctors are still in need of domperidone. We hypothesize that in normal dosages QT-prolongation is relatively infrequent and we expect we can identify clear risk factors that may guide doctors in safe prescribing of domperidone. In order to test this hypothesis, an observational study will be designed. All patients aged 18 years and older who start with domperidone while hospitalised in the Erasmus MC will be included. Excluded are patients who do not give informed consent, who are incompetent and who suffer from the congenital prolonged QT-syndrome.

Primary outcome will be QT time on the ECG, performed 30-60 minutes after the fourth dosage of domperidone. Secondary outcome will be a continuous QT-time measurement during 24 hours, starting after the fourth dosage.

We will look into the following potential risk factors:

- serum concentration of domperidone 30-60 minutes after the fourth dosage of domperidone

- pharmacogenetics (CYP3A4, CYP1A2, CYP2E1)

- general patient characteristics (age, gender, body weight, comorbidities, renal and hepatic function, serum electrolyte parameters)

- domperidone dosage

- comedication.

We expect to include 300 patients in one year.

Doel van het onderzoek

In literature, domperidone has been linked to QT-prolongation resulting in acute cardial dysrythmias and sudden death. However, in practice doctors are still in need of domperidone. We hypothesize that in normal dosages QT-prolongation is relatively infrequent and we expect we can identify clear risk factors that may guide doctors in safe prescribing of domperidone.

Onderzoeksopzet

1-2 days after starting domperidone.

Onderzoeksproduct en/of interventie

None. It concerns an observational study.
Domperidone is prescribed as part of usual care.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- new prescription of domperidone while hospitalised in the Erasmus Medical Center

- age 18 years and older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- no informed consent

- terminally ill patient

- incompetent patient

- congenital prolonged QT-syndrome

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40915
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4384
NTR-old	NTR4515
CCMO	NL49083.078.14
OMON	NL-OMON40915

Resultaten

Samenvatting resultaten
None.