Hartritmestoornissen (QT-verlenging op het ECG) door domperidon

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28199

Source
NTR

Brief title
QT-DOM

Health condition

QT-prolongation, cardiac dysrythmias

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Application is under consideration.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

QT-time on 24 hour (continuous) ECG

Several characteristics will be collected in order to establish the potential association of these characteristics with the primary outcome:

- 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.

Study description

Background summary

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.

Study objective

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.

Study design

1-2 days after starting domperidone.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

- age 18 years and older

Exclusion criteria

- no informed consent

- terminally ill patient

- incompetent patient

- congenital prolonged QT-syndrome

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	300
Type:	Anticipated

Ethics review

Not applicable

Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40915
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
None.