QT prolongation when using domperidone: prevalence and associated risk factors

Published: 15-06-2014
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To assess the prevalence of QT-prolongation in patients who are prescribed domperidone as part of usual care, and to assess potential risk factors for that QT-prolongation.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON40915

Source
ToetsingOnline

Brief title
QT prolongation when using domperidone

Condition

- Cardiac arrhythmias

Synonym
cardiac dysrhythmia, QT prolongation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bloodlevel, domperidone, pharmacogenetics, QT prolongation

Outcome measures

Primary outcome

Primary endpoint is QTc-time on ECG, performed 30-60 minutes after the fourth dosage of domperidone (or later, when necessary, but never earlier due to steady state).

Secondary outcome

- QTc trended over a 24-hour period in the subsample of the study population.

- QTc difference from baseline (defined as the QTc time at start of the 24 hour period), trended over a 24-hour period

- Occurence of arrthymias (Torsade de Pointes and VT/VF)

- blood level of domperidone

- pharmacogenetic profile

A number of potential risk factors (among which blood level and pharmacogenetic profile) will be collected, for which the association with QT prolongation will be determined.

Study description

Background summary

Domperidone has been shown to cause QT prolongation and sudden cardiac death.
On the other hand, domperidone is still needed as an effective antiemetic,

especially in patients with Parkinson*s disease. Therefore, doctors need additional information on the actual prevalence of QT-prolongation in everyday routine practice, as well as on risk factors associated with QT-prolongation. Such information will guide safe prescription practices.

Study objective

To assess the prevalence of QT-prolongation in patients who are prescribed domperidone as part of usual care, and to assess potential risk factors for that QT-prolongation.

Study design

Observational study

Study burden and risks

For each patient one blood sample will be drawn (30-60 minutes after the fourth dosage of domperidone; necessary for serum level and for pharmacogenetics) and an ECG will be performed (at the same time). A small sample of patients will be monitored with a 24 hour ECG monitor.
Domperidone is only given as part of routine usual care, so no pharmacotherapeutical interventions are carried out. In case a clinically relevant QT-prolongation is discovered, the doctor of the patient will we adviced to switch to another antiemetic drug. The doctor will also be informed about any other cardiac dysrhythmias discovered on the ECG. Finally, the doctor will be informed on pharmacogenetic disorders.

Contacts

Public
Erasmus MC

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 years or older
- Starting with domperidone while in hospital (patients already on domperidone when admitted to hospital, may be included as well)

Exclusion criteria

- Not providing informed consent
- Incompetent
- Terminally ill
- Congenital prolonged QT-syndrome

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	300
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Motilium
Generic name:	Domperidone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-06-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-07-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28199
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2014-001769-29-NL
CCMO	NL49083.078.14
OMON	NL-OMON28199