QTc-time prolongation when using two or more QTc-time prolongating drugs: prevalence and associated risk factors

Published: 31-07-2015
Last updated: 19-04-2024

To assess the prevalence of QTc-prolongation in patients who are prescribed two or more QTc-prolongating drugs as part of usual care, and to assess potential risk factors for that QTc-prolongation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON42786

Source
ToetsingOnline

Brief title
QTc-time when using two or more QTc-prolongators (QT-INTERACT)

Condition

- Cardiac arrhythmias

Synonym
heart rhythm disorders, QTc time prolongation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: KNMP

Intervention

Keyword: drug-drug interaction, ECG, QTc-time

Outcome measures

Primary outcome

Primary endpoint is QTc-time on ECG, performed at the moment of tmax of the lastly added drug (or in case of starting at the same time, at the moment of the longest tmax).

Secondary outcome

Potential risk factors for QTc time prolongation. The following parameters will be collected as potential risk factors for QTc prolongation:

- General patient characteristics: age, gender, race, bodyweight, length, comorbidities, liver function parameters, renal function parameters, serum electrolyte parameters
- Dosage of the interacting drugs
- Comedication
- Blood concentration levels of the interacting drugs, when these have been determined.
- Pharmacogenetic parameters when these have been determined.

Study description

Background summary

Several drugs have been shown to cause QTc prolongation and sudden cardiac death and the risk increases when such drugs are combined. However, the exact magnitude of the problem is unknown making it difficult for doctors to interpret the drug-drug interaction alert on QTc-time prolongation. Therefore,

doctors need additional information on the actual prevalence of QTc-prolongation in everyday routine practice, as well as on risk factors associated with QTc-prolongation when combining two or more QTc-prolongating drugs. Such information will guide safe prescription practices and may assist in the development of a clinical rule, facilitating the correct handling of this drug-drug interaction alert.

Study objective

To assess the prevalence of QTc-prolongation in patients who are prescribed two or more QTc-prolongating drugs as part of usual care, and to assess potential risk factors for that QTc-prolongation.

Study design

Observational study

Study burden and risks

For each patient an ECG will be performed. All drugs are only given as part of routine usual care, so no pharmacotherapeutical interventions are carried out. In case a clinically relevant QTc-prolongation is discovered, the doctor of the patient will we adviced to switch to another drug regimen. The doctor will also be informed about any other cardiac dysrhythmias discovered on the ECG.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 years or older
- Using a combination of two or more QTc-time prolongating drugs (either already in use before hospitalization or newly started).

Exclusion criteria

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

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2015
Enrollment:	500

Type:	Actual

Ethics review

Approved WMO Date:	31-07-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-03-2016
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL53580.078.15