QTc-prolongation in the use of antidepressants for anxiety-disorders

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

Summary

ID

NL-OMON38604

Source
ToetsingOnline

Brief title
QT-prolongation in AD use in Anxietydisorders (QADA)

Condition

- Cardiac arrhythmias

Synonym
Long QT syndrome, LQTS

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: misschien kan onderzoeker gebruik maken van een subsidie binnen parnassia.

Intervention

Keyword: Antidepressants, Anxiety Disorders, QTc-interval prolongation

Outcome measures

Primary outcome

The main study parameter is the incidence of QTc-prolongation caused by different types of antidepressants use, measured by the difference in QTc-time between baseline and after six weeks of antidepressant use within one person.

Secondary outcome

We investigate whether there is a difference between the different types of antidepressants (serotonin-reuptake inhibitors, serotonine-noradrenaline reuptake inhibitors, tricyclic antidepressants, mono-amine oxidase inhibitors) on the prolongation of the QTc-interval. In addition we will investigate if there are specific risk factors that contribute to this prolongation.

Study description

Background summary

The QTc-interval is the time, corrected for the heart rhythm, which is necessary for the heart muscle cells to repolarise. However, if this interval increases too much and the cells do not repolarise simultaneously, there may occur potentially fatal arrhythmias as Torsades de Pointes. Prolongation of the QTc-interval may occur as a side effect of the use of antidepressants. However, the exact incidence and clinical relevance of this side effect, especially in younger people, is yet unknown.

Study objective

The main objective is to investigate whether and to what extent the QTc-time prolongs with the use of different types of antidepressants in adults treated with antidepressants for anxiety disorders. In addition we will investigate if there are differences between the types of antidepressants and if there are

specific risk factors that contribute to this prolongation.

Study design

prospective cohort study.

Study burden and risks

Patients need to fill in a questionnaire and need to undergo at least two ECG investigations. If deemed necessary (in case of QTc-prolongation) a blood sample analysis will take place, this is care as usual. These interventions can be stressful. Data that will be collected by this questionnaire are: DSM IV diagnosis, type of antidepressant and dosage, sex, length, weight, age, medical history (e.g. liver/renal disorders, heart suffering, diabetes), family history (e.g. for acute heart death), medication use and substance abuse. A benefit for the patients is that they undergo additional ECG checks (compared to treatment according to the guidelines), providing the early detection of abnormalities. If a prolonged QTc-interval of 500 ms or more is found, patients will be referred to the cardiologist. There is a risk that a previously unknown deviation is discovered at the ECG, which may affect the future of the patient. Patients will be notified of these risks in advance.

Contacts

Public
Parnassia (Den Haag)

Lijnbaan 4
Den Haag 2512 VA
NL
Scientific
Parnassia (Den Haag)

Lijnbaan 4
Den Haag 2512 VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age between 18 and 55 years.
- Under treatment of the department of Anxiety Disorders, PsyQ, The Hague.
- Indication to start with antidepressant medication and not known to have a contra-indication to start with this kind of medication, e.g. severe liver dysfunction, long QT-syndrome, recent myocardial infarct.
- Able and willing to give informed consent.

Exclusion criteria

- Patients who had used already antidepressant medication in the 6 weeks prior to the inclusion.
- Patients who already use QT-prolonging anti-arrhythmic medication (e.g. sotalol, amiodarone).
- Patients who do not meet inclusion-criteria.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2014

Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Electrocardiograph
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-07-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL45858.058.13