Renal cystic disease in lithium treated patients
assessment by MRI and renal ultrasound.

Published: 09-01-2014
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Primary Objective: The main objective of this study is to determine whether MRI and ultrasound are capable to distinguish the existence and extent of microcysts in a Dutch population of lithium treated patients.Secondary Objective(s): to determine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON38734

Source
ToetsingOnline

Brief title
Detecting renal cystic disease

Condition

- Renal disorders (excl nephropathies)

Synonym
microcysts, small renal cysts

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Lithium, MRI, renal cysts, ultrasound

Outcome measures

Primary outcome

The prevalence and a semi-quantitative measurement of the number and size of microcysts in lithium treated patients.

Secondary outcome

Relation between MRI and ultrasound results * presence of microcysts * and clinical parameters (duration of lithium therapy, plasma lithium concentration, baseline plasma creatinine, sodium and potassium concentration and baseline urinary osmolality)

Study description

Background summary

Lithium therapy is associated with several forms of renal injury, including the development of microcysts. Importantly, these microcysts distinguish lithium treated patients from other patients with renal disease. The microcysts originate from distal and collecting tubules and are localized in both the cortex and the medulla. Up until now these microcysts have been described predominantly in patients with advanced renal disease. Little is known about the stage in witch these microcysts develop and whether an association exists between these microcysts and other symptoms of renal injury

Study objective

Primary Objective: The main objective of this study is to determine whether MRI and ultrasound are capable to distinguish the existence and extent of microcysts in a Dutch population of lithium treated patients.

Secondary Objective(s): to determine the relation between
- duration of lithium exposure and renal microcysts
- the presence of LAR and renal microcysts

- to determine whether number and or extend of microcysts in lithium treated patients is related to duration of lithium therapy.

Study design

This is a observational cross-sectional study.

Study burden and risks

Subjects will be asked to visit the out-patient clinic once. During this visits, Renal MRI and renal ultrasound will be performed. This is a procedure that takes about 1,5 hour of there time. Since no intravenous contrast is necessary this procedure is not invasive for the subject and of little inconvenience.
Subject may be confronted with incidental findings

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

Inclusioncriteria (patients)
- patients (m/f, age *18 years) with a bipolar disorder treated with lithium

Exclusion criteria

- general contra-indications for participation in a trial:
- inability to give informed consent
- pregnancy
- unstable psychiatric condition ;- Inability to undergo MRI.
- standard contra-indications for MR (in accordance with the hospital protocol), such as the presence of metallic fragments, clips or devices including implantable pacemakers and implantable cardioverter-defibrillators, extreme overweight, claustrophia

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	09-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL45606.029.13