The Bipolar Lithium Imaging Scan Study: imaging lithium in the brain of BD patients.

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Primary Objective: To confirm that the lithium headcoil is capable of measuring lithium signals related to clinical doses in the brains of BD patients (MDR, art 82), and then to establish the correlation of neuroimaging data of lithium...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Manic and bipolar mood disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON53664

Source
ToetsingOnline

Brief title
BLISS

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolar disorder; manic depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bipolar disorder, Lithium, MRI, Neuro-imaging

Outcome measures

Primary outcome

Concentration of lithium in the brain, using average whole-brain concentration

and concentrations in ROI*s (predefined regions of interest).

Secondary outcome

- Serum lithium level

- Longitudinal clinical lithium response

Study description

Background summary

Lithium treatment is considered the first option in pharmacological treatment of bipolar disorder (BD). Individual responses however vary greatly, which undermines rapid stabilization in many BD-patients. Novel developments in neuro-imaging enable us to determine the concentration and distribution patterns of lithium in the brains of BD-patients. These highly specialized neuro-imaging data are not yet available and is expected to provide groundbreaking information on how lithium exerts its therapeutic effects, thereby potentially increasing the current moderate success rates of lithium treatment.

Study objective

Primary Objective:
To confirm that the lithium headcoil is capable of measuring lithium signals related to clinical doses in the brains of BD patients (MDR, art 82), and then to establish the correlation of neuroimaging data of lithium concentrations in the brain of BD patients with longitudinal clinical lithium treatment outcome measures.

Secondary Objectives:
To establish the correlation of neuroimaging data from 7T lithium-MRSI in BD

patients with serum lithium levels.

Study design

We will perform 7T lithium-MRSI in BD-patients who have recently (i.e within 2 weeks) started with lithium as part of their regular treatment protocol. Subjects will be recruited from an already ongoing longitudinal naturalistic cohort-study (BINCO-study). As soon as participants in the BINCO-study start to prepare for lithium treatment as part of their regular treatment protocol, they will be invited for a separate informed consent procedure for the current study.

After the informed consent procedure and within 2 weeks of reaching therapeutic blood levels of lithium, study subjects will undergo one 7T lithium MRSI scan at our scan facility at LUMC.

At the same day;
- blood will be drawn to determine lithium serum levels and
- two validated, short questionnaires addressing actual mental state will be carried out: the Young Mania Rating Scale (YMRS; Young et al, 1978) and Quick Inventory of Depressive Symptoms (QIDS; Rush et al, 2003).

Longitudinal clinical lithium treatment outcome will be assessed using the Retrospective Criteria of Long-term Treatment Response in Research Subjects With Bipolar Disorder scale, also known as the ALDA scale (Manchia et al, 2013). This assessment will take place as part of the BINCO-study at 12 months follow up.

In the process of writing this protocol, we have asked and received input of the chair of the patient organization for BD patients in the Netherlands, ensuring patient participation on several (non-technical) aspects in the current protocol.

Study burden and risks

Subjects will undergo 7T lithium MRS imaging. Risks are estimated as very low: please refer to the separate IMDDs as part of this submission. Participants will not benefit directly from 7T lithium MRS imaging.

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

In order to be eligible to participate in our study, a subject must meet all of the following criteria:
* Aged 18 years or above
* In the last 12 months clinically diagnosed with bipolar disorder type I or II and confirmed BD diagnosis according to the SCID-I
* One out of two criteria below:
o Start of specialized outpatient treatment for BD or
o Admission due to first mania
* Starting lithium treatment as part of their regular treatment
* Written informed consent

Exclusion criteria

* Participants who cannot read, speak or understand Dutch
* Unable to provide informed consent: this will be assessed during the informed consent procedure by trained research personnel. They will also consult the clinicians involved in the study.

* Drug or alcohol abuse over a period of six months prior to the study participation
* Contra-indications for an MRI/MRSI

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-03-2024
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Philips Achieva 7T MRI en Rapid Biomedical lithium headcoil interface
Registration:	No

Ethics review

Approved WMO Date:	03-07-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	13-09-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (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	NL80214.058.22