Measurement of lithium pharmacokinetics with the Medimate Multireader® in cluster headache patients

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The primary objective of this study is to investigate whether differences in patient specific pharmacokinetic properties, both dynamic and absolute, reveal the difference in response to lithium treatment. The pharmacokinetic properties which will be...

Ethical review	Approved WMO
Status	Pending
Health condition type	Headaches
Study type	Observational invasive

Summary

ID

NL-OMON34105

Source
ToetsingOnline

Brief title
Measurement of lithium pharmacokinetics in cluster headache patients

Condition

- Headaches

Synonym
Cluster headache, Horton syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Medimate BV

Intervention

Keyword: Cluster headache, Lithium prophylaxis, pharmacokinetics

Outcome measures

Primary outcome

To determine whether there is a correlation between the frequency of cluster headache attacks and the absminLi.

Secondary outcome

We will describe the relation between the t1/2 and 12h-Li and the frequency of attacks. Furthermore, we will compare the results of the Liattack with the Licontrol measurements. Finally, we will evaluate the use of additional medication and the kidney function.

Study description

Background summary

Patients who have unsuccesfully been treated with verapamil as prophylactic medication for their CH might benefit from lithium as maintenance prophylaxis. The clinical outcome under lithium treatment differs between patients. Some patients are free from clusterheadache attacks, whereas others still experience attacks. Nevertheless, these attacks are less frequent, shorter in duration and / or less severe. Specific pharmacokinetic properties have not been studies as potential cause of the difference in clinical outcome. In this study we would like to assess both dynamic, the elimination half life (t1/2), and absolute properties, concentrations, of lithium in CH patients. It is hypothesized that a correlation between the absminLi, the minimal concentration of lithium prior to the intake of lithium, and the amount of clusterheadache attacks can be found. Furthermore, the relation between t1/2 and the concentration 12 hours post intake (12h-Li) on one hand and the frequency of attacks on the other hand, might reveal the response of a patient to lithium medication. Additionally, the lithium concentration during an attack (Liattack) is compared

with a matched-control measurement (Licontrol).

Study objective

The primary objective of this study is to investigate whether differences in patient specific pharmacokinetic properties, both dynamic and absolute, reveal the difference in response to lithium treatment. The pharmacokinetic properties which will be assessed are the absminLi, t1/2 and 12h-Li. In addition, the lithium concentration during an attack will be compared to a contol measurement, Licontrol.

Study design

This is an observational study in which cluster headache patients with and without attacks under lithium prophylaxis are included.

Study burden and risks

After the vena puncture, a bruise or hematome can form at the injection site. The patients can have little wounds or crusts from the finger pricks.

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

Diagnosed with cluster headache according to "The International Classification of Headache Disorders, 2nd Edition". The patients should have a stable lithium intake for at least 3 weeks.

Exclusion criteria

Patients with significant renal disease which may interfere with the study, or patients with other significant neurological or disabling diseases than CH, are excluded from this study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2010
Enrollment:	22
Type:	Anticipated

Medical products/devices used

Generic name:	Multireader®
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-11-2010
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	NL34136.058.10