

Long-term effects of lithium on the motoric and/or psychological development of children who are exposed to lithium during pregnancy.

Published: 18-03-2008

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The objective of the study is to investigate the long-term effects of lithium on the development of children who are exposed to lithium during pregnancy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Neurological disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON32087

Source

ToetsingOnline

Brief title

Outcome of lithium exposure in utero

Condition

- Neurological disorders congenital
- Foetal complications
- Manic and bipolar mood disorders and disturbances

Synonym

long-term effects of lithium exposure, outcome of exposure to lithium

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: Development, Lithium, Long-term effects, Pregnancy

Outcome measures

Primary outcome

Differences in physical and psychological development between children who are exposed to lithium in utero, and children who are not.

Secondary outcome

Not applicable

Study description

Background summary

Since 1950 lithium is used as a drug against bipolar disorder because of its antimanic and antidepressive effect. Bipolar disorder is common in women in the fertile phase, so a lot of research has been done about the influence of the use of lithium on pregnancy and on the foetus. Especially congenital disorders have been studied. Recent studies suggest that lithium would enlarge the risk on congenital heart disorders and a large birth weight. Besides that there are a lot of case reports that report other complications, like rythm disturbances and thyroid dysfunction, but a significant difference could never be proved. Animal studies suggest that lithium could influence the developing brain badly. There has been almost no research after possible long-term effects of lithium. The only publication, that did not show differences, was based on incomplete data. Still lithium could have an effect on the motoric and/or psychologic development of a child. This is why a more reliable study will be done after the possible long-term effects of lithiumexposure during pregnancy.

Study objective

The objective of the study is to investigate the long-term effects of lithium on

the development of children who are exposed to lithium during pregnancy.

Study design

Het onderzoek bestaat uit een vragenlijst voor de ouders en een bezoek van ouder en kind aan het Leids Universitair Medisch Centrum. De enquête bevat vragen over de sociale situatie van het kind, de lichamelijke en de psychosociale ontwikkeling van het kind. Tijdens het bezoek aan het LUMC zal het kind lichamelijk en psychologisch onderzocht worden.

Study burden and risks

The visit will take about 2 hours. The examination is not invasive and there are no risks associated with participation.

Contacts

Public

Leids Universitair Medisch Centrum

Albinusdreef 2
2300 RC Leiden
Nederland

Scientific

Leids Universitair Medisch Centrum

Albinusdreef 2
2300 RC Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Lithium exposure during pregnancy

Birth in the LUMC

Exclusion criteria

Not being exposed to lithium during pregnancy

Not being born in the LUMC

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	10-11-2007
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

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	NL20063.058.07