National postpartum psychosis prevention study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Postpartum and puerperal disorders
Study type	Observational invasive

Summary

ID

NL-OMON47010

Source
ToetsingOnline

Brief title
NP3-Study

Condition

- Postpartum and puerperal disorders
- Manic and bipolar mood disorders and disturbances

Synonym
"puerperal psychosis", postpartum psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Nuts Ohra

Intervention

Keyword: Postpartum psychosis, Prevention, Psychopharmaca, Relapse

Outcome measures

Primary outcome

Primary outcome will be peripartum relapse (during pregnancy or within 3 months postpartum): any episode fulfilling DSM-IV criteria for mania/depression/psychosis or any other episode, severe enough to warrant treatment.

Secondary outcome

Obstetric complications, neonatal adverse outcome, infant neurodevelopment.

Blood cells and serum biomarkers predictive for relapse.

Study description

Background summary

Women with a history of bipolar disorder or postpartum psychosis are at extremely high risk (22 - 75%) of relapse peripartum (during pregnancy or within 3 months postpartum). Some small studies demonstrated that prophylactic pharmacotherapy peripartum is associated with a lower chance of relapse. However, this needs to be balanced against the risk for potential negative effects associated with the neonate.
Furthermore, there is a lack of studies on the development of infants born to women with bipolar disorder.

Study objective

The primary aim of this study is to investigate if prophylactic pharmacotherapy peripartum is associated with a lower chance of relapse peripartum. In more detail, we will investigate if there is a difference in relapse between patients that used psychopharmaca during pregnancy and postpartum, and patients that only used medication postpartum. We hypothesize that psychopharmaca use during pregnancy and postpartum is associated with the lowest chance of relapse.

The secondary aims of the study are:
1. Investigate what psychopharmaca in particular is associated with the lowest chance of relapse. Antipsychotics (e.g. quetiapine, olanzapine or haloperidol) and mood stabilizers (lithium, depakine, carbamazepine or lamotrigine) are most commonly used (separate or a combination of a moodstabilizer and antipsychotic medication) to reduce peripartum relapse. With respect to the present literature, we hypothesize that a monotherapy with the mood stabilizer lithium is associated with the lowest chance of relapse peripartum.
2. Investigate the timing, dosage and duration of pharmacotherapy in relation to the chance of relapse peripartum. We hypothesize that more extensive use (longer/higher dosage) of prophylactic pharmacotherapy is associated with a lower chance of relapse.
3. Investigate obstetric complications and neonatal outcome in relation to psychiatric illness and pharmacotherapy. We hypothesize that pharmacotherapy peripartum is associated with a higher incidence of obstetric complications and adverse neonatal outcome.
4. Investigate blood cells and serum biomarkers to predict peripartum relapse. We hypothesize that auto-immune thyroid disease, and abnormalities of angiogenic factors are more common in relapse patients compared to non-relapse patients and women without a psychiatric history.
5. Investigate recovery (e.g. experience of mild mood complains and somatic complains) twelve months after a pregnancy. We hypothesize that patients with a history of bipolar disorder and/or a postpartum psychosis experience a more slow recovery pattern after pregnancy.
6. To assess children*s neurodevelopment between 2 and 5 years of age. We hypothesize that due to pharmacotherapy peripartum and the psychiatric illness of the mother the development will be delayed compared to the controls.
7. To assess the mental and general health women with a history of bipolar disorder or postpartum psychosis between 2 and 5 years postpartum.

Study design

A prospective naturalistic cohort study, enrolled pregnant women will be treated as usual. Patients and controls will fill in a digital questionnaire at 32 weeks pregnancy and five time points postpartum (estimate time investment: 10 minutes each time). Furthermore, additional blood tubes will be taken off once during regular blood assessment, which occurs between 26 and 30 weeks of to investigate blood cells and serum biomarkers predictive for relapse.

Study burden and risks

No risks associated with participation. We estimate that participation will take in total 4 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Age > 18 years
- A history of bipolar disorder and/or postpartum psychosis
- Women who are able to complete Dutch questionnaires;Offspring: between 2 and 5 years of age

Exclusion criteria

None.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2013
Enrollment:	310
Type:	Actual

Ethics review

Approved WMO Date:	19-11-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL45670.078.13