The effect op sleep disturbance during pregnancy and perinatal period on postpartum psychopathology in women with bipolar disorder and/or history of postpartum psychosis

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Primary objective: To investigate whether sleep disturbances during pregnancy and/or in the perinatal period will predict postpartum psychopathology in women with an established diagnosis of bipolar disorder and/or a history of postpartum psychosis....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON37925

Source
ToetsingOnline

Brief title
SLEEPREG-BD

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Manic and bipolar mood disorders and disturbances

Synonym
bipolar disorder; postpartum psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Dimence (Deventer)
Source(s) of monetary or material Support: Dimence (Deventer),Dimence GGZ,ENO zorgverzekeraar

Intervention

Keyword: bipolar disorder, postpartum psychopathology, pregnancy, sleep

Outcome measures

Primary outcome

(1) the occurrence of psychiatric symptoms during the first four weeks

postpartum

(2) the number and type of any intervention started for impending psychiatric

symptoms during the first four weeks postpartum.

Secondary outcome

nvt

Study description

Background summary

Treatment of women with bipolar disorder during pregnancy and in the postpartum period is a major challenge. Decisions must be made about whether or not to take psychiatric medication while pregnant and after delivery, weighing the risks for the mother and the (unborn) child. Especially the postpartum period is associated with an increased risk for the onset or exacerbation of bipolar disorder (Kendell et al, 1987; Leibenluft 1996, Jones et al 2002) and maternal death (Jones et al 2005). In a study of Viguera et al (2011) 52 % of women with bipolar disorder developed a mood episode in the postpartum period (479 pregnancies/283 women). Subsyndromal symptoms were not investigated. Death, caused by a psychiatric illness (severe self-neglect or suicide), is highest for women in the year following delivery (Oates 2003, Lewis et al, 2007). In the first two weeks postpartum the risk of having an episode is highest: 25-30% with medication, and 70% without medication (Sitsen et al, 2011, Yonkers et al, 2011). Literature about subsyndromal symptoms in the postpartum is very scarce.

There is a much evidence for a relationship between sleep disruption and mood disorders. A recent review suggests that sleep disturbances frequently precede the onset of a bipolar mood episode by years and could be a long-term riskfactor for any kind of mood disorder (Ritter et al, 2011).
Sleep reduction has been postulated as the final common pathway in the onset of mania (Wehr et al, 1987) and frequently a temporal relation between sleep disruption and a mood change is seen (Bauer et al, 2006). Ross et al (2005) reviewed the association between sleep and perinatal mood disorders. This extensive review indicated that the interaction between sleep and perinatal mood disorders is significant. Preventing or decreasing sleep disturbance could be a cost-effective method for prevention and treatment of postpartum mood disorders. The authors stated that studies measuring both sleep and mood during the perinatal period will provide important information about causes, prevention and treatment of perinatal mood disorders. Only few studies assessed sleep disturbances in detail. In a prospective study (Bilzsta et al 2010), no difference in sleep-wake rhythm was found between women with bipolar disorder and healthy women. However, that study was limited by the very small sample size (23 patients versus 15 controls).
Women with postpartum psychosis may have a longer duration of labour and may be more likely to deliver at night than controls (Sharma et al 2004, 2003a). Sleep loss has been suggested as a final common pathway in the development of psychosis in vulnerable women (Sharma 2003b). In the various guidelines (APA 2002; CANMAT, update 2009, Yatham; NVvP, 2008; NICE 2006) there is no information about possible importance of delivery during daytime. To our knowledge there is no study addressing forced deliveries during daytime in relationship to postpartum psychopathology in bipolar disorder.

A better understanding of the impact of sleep disturbances during pregnancy and in the perinatal period on postpartum psychopathology could help the development of additional guidelines for prevention (and treatment) of postpartum psychosis in women at risk.

The aim of this prospective study is to investigate the role of altered sleep patterns during pregnancy and the perinatal period in women with bipolar disorder and/or a history of postpartum psychosis, whether such sleep-disturbances serve as a potential indicator and warning sign for psychopathology later in pregnancy and during the perinatal and postpartum periods, and whether early detection and management of sleep disturbances improves the subsequent course of psychopathology up to the end of the postpartum period.
In addition, the significance of mood symptoms (either syndromal or subsyndromal) during pregnancy as predictors of postpartum psychopathology will be investigated, as well as the influence of pharmacotherapy during pregnancy and/or the postpartum period on postpartum psychopathology, and the relationship between daytime delivery and postpartum psychopathology.

Study objective

Primary objective:
To investigate whether sleep disturbances during pregnancy and/or in the perinatal period will predict postpartum psychopathology in women with an established diagnosis of bipolar disorder and/or a history of postpartum psychosis.

To investigate whether psychiatric symptoms, either syndromal or subsyndromal, during pregnancy predict postpartum psychopathology.

Secondary objectives:
To investigate whether the use of psychotropic medication during pregnancy and the perinatal period is associated with a decreased risk of postpartum psychopathology

To investigate whether daytime labour/delivery is associated with a decreased risk of postpartum psychopathology

To investigate whether the use of the Edinburgh Postnatal Depression Scale predicts postpartum psychopathology in a population of pregnant women with bipolar disorder.

To investigate whether sleep disturbances early in pregnancy predicts the occurrence of subsyndromal mood symptoms or syndrome mood episodes later in pregnancy.

Study design

This is a prospective, observational, naturalistic, non-interventional study.

Study burden and risks

Participants will have to make one extra visit at entry of the study. They will have to complete a simple mood chart (Lifechart) via internet on a daily or nearly-daily basis during the entire study (in some patients this may already be part of routine monitoring during treatment).
In week 13 and week 26 of pregnancy and from week 38 of pregnancy to week 4 postpartum they have to complete a sleep-diary. At week 13 and week 26 of pregnancy and from week 38 of pregnancy to week 4 postpartum and in week 12 postpartum they will have to complete various questionnaires. Participants will have to wear an actimeter in week 13 and 26 of pregnancy and from week 38 of pregnancy till week 4 postpartum.
Psychiatric and medical treatment will be given as usual. The study imposes no additional risks to the participant and her child.

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

bipolar disorder and/or postpartum psychosis in history
AND
pregnancy

Exclusion criteria

patients without informed consent
patients with current severe substance abuse

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2012
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	NL37319.029.11