Research Protocol

Mood Disorders during pregnancy - effects on maternal health and child development.

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Background:

Mood disorders affects 10-15% of pregnant women, with depression as the most prevalent.[1,2] A proportion of these women will receive pharmacological treatment during their pregnancy. Since the discovery of thalidomide's teratogenic potential in the 1960s[3,4] focus has been on the adverse effects on the embryo/ fetus. Surprisingly, few studies have investigated maternal aspects of psychiatric disease during pregnancy, including pattern of use, effectiveness of the treatment, obstetric outcome (including pre-eclampsia[5]), and impact on breastfeeding[6] of both the underlying disease and pharmacological treatment. Furthermore, the potential effect of an untreated maternal psychiatric disease on fetal development is undetermined.

Given the quality of data within the Danish National Birth Cohort, this study allows us to potentially delineate the effects of underlying maternal depression from that of antidepressant exposures during pregnancy, with regards both obstetric outcome and child development. Importantly, the data allow us to investigate consequences of maternal mood disorders in respect of lifestyle, pattern of medication use, and breast-feeding. The studies will continue the work previously performed by the research group drug safety and treatment of mood disorders during pregnancy.[5,7-14]

Research Question

Is the presence and management (i.e. treatment or discontinuation of treatment) of mood disorders during pregnancy associated with adverse pregnancy outcomes, puerperal depression, suboptimal breastfeeding, or changes in child development.

Methods

Prospective cohort study using data from the Danish National Birth Cohort

Study Population and Setting

The complete cohort of individuals in the Danish National Birth Cohort (DNBC) study.

Mood disorder

Mood disorders during pregnancy: Mood disorder will be defined according to the questions in the interview 1 and 2. We will further classify the degree and type of the mood disorder on the basis of the symptoms score in the interview 2.

Drug exposure:

Exposure to antidepressants during pregnancy: Use of SSRIs and other antidepressants during pregnancy will be de-fined according to maternal self-reported use. Women who self-report use or who received at least one dispensing will be classified as exposed. Timing and duration of exposure will also be calculated based on maternal self-report.

Outcome measures:

1. Measures of maternal health during pregnancy among women with mood disorders: patterns of medication use, lifestyle factors (i.e. role of maternal diet and vitamin), maternal metabolic outcomes (e.g GDM), and adverse obstetric outcomes (e.g. pre-eclampsia).
2. Puerperal depression.
3. Initiation and duration of breast-feeding
4. Child health and development.

Statistical Analysis

One-way analysis of variance, the wilcoxon rank-sum test, or Fisher's exact test will be used to estimate differences in baseline characteristics, timing of questionnaires and maternal mental well-being between the groups using Stata 11 (Stata, College Station, TX). We will construct a model using directed acyclic graphs as proposed by Greenland et al[15] to identify potential sources of existing bias and to avoid introducing bias through inappropriate adjustment (i.e. controlling for potential intermediates).

Ethics

The project is approved by the Danish Dataprotection Agency.

Project team

The project involves collaboration between researcher with a background in epidemiology, obstetrics, psychiatry and pharmacology in both Denmark and Australia. The group includes Professor Jørn Olsen (epidemiology), Professor Poul Videbech (psychiatry) associate professor Bodil Hammer Bech (epidemiology), post doc Luke Grzeskowiak (pharmacology), associate professor Vicky Clifton (obstetrics), and assistant professor Lars Henning Pedersen (obstetrics).

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