

# Antidepressants during pregnancy: risk-benefit study for mother and child

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
20/12/2005	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
20/12/2005	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
05/01/2010	Mental and Behavioural Disorders	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

CCMO P03.0335, UMC U 03-024; NTR346

## Study information

### Scientific Title

**Acronym**

OAZE (Dutch: Onderzoek Antidepressiva tijdens Zwangerschap, een Evaluatie)

**Study objectives**

The use of modern antidepressants during pregnancy is associated with changes in foetal movement and development and can lead to serious withdrawal syndromes after birth. Antidepressant use as well as discontinuation of medication during pregnancy will have an effect on the mental development of the child.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Received from the local medical ethics committee

**Study design**

Multicentre, non-randomised, two armed, parallel group trial

**Primary study design**

Interventional

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Depression and pregnancy

**Interventions**

The study is a prospective observational study and therefore there are no interventions. Subjects enter the study as antidepressant user (group A) or as having stopped taking medication (group B).

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Antidepressants

**Primary outcome(s)**

The effects of antidepressants are evaluated through measurements of foetal movement and development, registration of withdrawal syndromes after birth and measurement of child behaviour and development until the age of 2 years. Of 200 women who are on antidepressants during pregnancy (group A) and 200 women who stopped medication in the first trimester (group B) the social-economical status, smoking/drinking habits, co-medication, mental status (Edinburgh Depression Scale and State Trait Anxiety Inventory), specific pregnancy anxiety and blood level of the antidepressant are registered at 17, 28 and 37 weeks of pregnancy. Ultrasound recording of the foetal movements is also planned around these three time points.

after delivery pregnancy outcome and observations of the baby during the first 10 days after birth are registered using the Finnigan score on withdrawal symptoms. Foetal drug exposure and neonatal drug elimination kinetics are estimated using umbilical cord blood and a blood sample of the child several hours after birth.

At 3 months, 8 months and 2 years after birth, behaviour and mental development are tested using the CBCL, child behaviour list and the IBQ infant behaviour questionnaire. The results of the two study groups A and B are compared. Dose-effect relations and level of exposure-effect relations are evaluated in relation to the severity of the withdrawal symptoms.

### **Key secondary outcome(s)**

1. The positive effects of antidepressant use on the mental state of the mother during pregnancy and delivery versus the effects of discontinuation of pharmacotherapy
2. Pharmacokinetic changes of the different antidepressants in the three phases of pregnancy

### **Completion date**

23/12/2006

## **Eligibility**

### **Key inclusion criteria**

Women who are pregnant and use one of the modern antidepressants (selective serotonin re-uptake inhibitor [SSRI] and non-SSRI) are included at 16 weeks of pregnancy, group A. Women who stopped taking antidepressants in the first trimester or just before pregnancy are included in group B. Women must be willing and give informed consent and must be able to read in Dutch in order to fill in the questionnaires.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Co-medication with a similar or higher pregnancy risk factor
2. Alcohol or drug addiction

### **Date of first enrolment**

12/07/2003

### **Date of final enrolment**

23/12/2006

## **Locations**

## **Countries of recruitment**

Netherlands

## **Study participating centre**

**University Medical Center Utrecht**

Utrecht

Netherlands

3508 GA

## **Sponsor information**

### **Organisation**

University Medical Centre Utrecht (UMCU) (Netherlands)

### **ROR**

<https://ror.org/04pp8hn57>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Eli Lilly Nederland BV (The Netherlands)

### **Funder Name**

Pfizer Netherlands (The Netherlands)

### **Funder Name**

The Netherlands Brain Foundation (Hersenstichting Nederland) (The Netherlands)

### **Funder Name**

Stichting Doelmatig Geneesmiddelengebruik Midden Nederland (The Netherlands)

**Funder Name**

Arijan Porsius Fonds (The Netherlands)

## Results and Publications

### Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#"><u>Results article</u></a>	results	01/07/2009		Yes	No