

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Quality of life

## Participant information sheet

## 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 measure**

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.

### **Secondary outcome measures**

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

### **Overall study start date**

12/07/2003

### **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

### **Age group**

Adult

**Sex**

Both

**Target number of participants**

400

**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)

**Sponsor details**

PO Box 85500

Utrecht

Netherlands

3508 GA

**Sponsor type**

University/education

**Website**

<http://www.umcutrecht.nl/zorg/>

ROR

## 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

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### 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?
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[Results article](#)

results

01/07/2009

Yes

No