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

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] 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

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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

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

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?

Results article	results	01/07/2009	Yes	No