Antidepressants during pregnancy. Risk-benefit study for mother and child.

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The use of modern antidepressants during pregnancy is associated with changes in fetal movement and development and can lead to seroius withdrawal syndromes after birth. Antidepressant use as well as discontinuation of medication during pregnancy...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22370

Bron
Nationaal Trial Register

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

Aandoening

Antidepressant use, pregnancy, depression, anxiety, neonatal withdrawal syndrome, developmental disorder.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, The Netherlands
Overige ondersteuning: Hersenstichting Nederland, Arijan Porsius Fonds, Stichting doelmatig Geneesmiddelengebruik Midden Nederland.
Unrestricted educational grands from:
Eli Lilly Nederland, Pfizer Inc USA.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The effects of antidepressants are evaluated through measurements of fetal movement and development, registration of withdrawal syndromes aftr birth and measurement of child behaviour and development till 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 staus (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 fetal 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 Finniganscore on withdrawal symptoms. Fetal 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.

Toelichting onderzoek

Achtergrond van het onderzoek

The use of modern antidepressants (SSRIs and non-SSRIs) is expandig, also in pregnant women. Although until now no increased risk for pregnancy loss or major structural malformations are documented, risk for neurobehavioal disorders or long term side effects are not jet established.
Antidepressant use during pregnancy can cause neonatal withdrawal effects. Discontinuation of antidepressants during pregancy on the other had can lead to re-emergence of the psychiatric disorder. Stress and anxiety are known for their harmful effects on the fetus. They may impair development and account for behaviour abnormalities of the child. To stop or continue treatment when a patient is pregnant is a great dilemma health care workers are facing. Moreover because they are lacking scientifical knowledge to make a profound risk-benefit decision. The OAZE-study is a prospective observational study among 400 women on the effects of continuation versus discontinuation of modern antidepressants during pregnancy.
By means of standardised questionaires the mental and physical sate of the mother and child are followed after the first trimester of pregnancy until 2 years after delivery. Using ultrasounc and blood samples additional data are collected on fetal behaviour, level of drug exposure and pharmacokinetics. With the rsults of the OAZE-study policies can be made regarding the use of antidepressants during pregnancy and regarding the required extra neonatal care after birth.

Doel van het onderzoek

The use of modern antidepressants during pregnancy is associated with changes in fetal movement and development and can lead to seroius 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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women who are pregnant and use one of the modern antidepressants (SSRI and non-SSRI) are included at 16 weeks of pregnancy, group A. Women who stopped taking atnidepressants 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Co medication with a similar or higher pregnancy risk factor;

2. Alcohol or drug addiction.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-07-2003
Aantal proefpersonen:	400
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-10-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL308
NTR-old	NTR346
Ander register	: CCMO P03.0335, UMC U 03-024
ISRCTN	ISRCTN25383361

Resultaten

Samenvatting resultaten
N/A