SMOK-study:
SSRI Medication in pregnant women: Effect on development of children.

Gepubliceerd: 18-10-2006 Laatst bijgewerkt: 18-08-2022

Regarding the facts that in the fetus serotonin is involved in the synthesis of serotonergic neurons (autoregulation) as well as in the development of target tissues such as specific parts of the brain, the use of SSRI (selective serotonin reuptake...

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

Samenvatting

ID

NL-OMON22808

Bron
NTR

Verkorte titel
SMOK

Aandoening

The use of SSRI by pregnant women.

Ondersteuning

Primaire sponsor: n.a.
Overige ondersteuning: n.a.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In the first week after birth and at 3 months post-term: Quality of general movements.
At the age of 2 years and 6 years: Motor and cognitive development.

Toelichting onderzoek

Achtergrond van het onderzoek

Infants of depressed mothers are at risk for developing cognitive and motor problems. A major depression often is treated with drugs, also in pregnant women, although the risk of the drug for the fetus is unknown. Approximately 2% of the Dutch pregnant women is using an SSRI (selective serotonin reuptake inhibitor) as antidepressant drug. SSRI's cross the placenta easily. The consequences of the use of an SSRI by the mother for the child remain to be determined. Short-term consequences are, among other things, withdrawal symptoms, convulsions, low Apgar score and prematurity. Long-term effects are insufficiently examined. Serotonin in detectable in the embryo very early, before the neurons are differentiated. It is involved in the morphogenesis of brain, heart, craniofacial epithelium and other structures. Both a deficiency as well as an excessive amount of serotonin changes the amount and development of neurons in the brain in animal models.
Hypothesis: The use of SSRI in pregnancy could lead to developmental problems in the fetus.
Objective of the study: To examine the consequences of the use of SSRI in pregnancy for motor and cognitive development of the child, in the short and long term.
Study-design: Prospective case-controlled.
Study population: 120 healthy newborn babies, of whom 60 have been exposed to SSRI in pregnancy; 30 normal controls and 30 infants of depressed mothers who did not use medication during pregnancy.

Doel van het onderzoek

Regarding the facts that in the fetus serotonin is involved in the synthesis of serotonergic neurons (autoregulation) as well as in the development of target tissues such as specific parts of the brain, the use of SSRI (selective serotonin reuptake inhibitor) in pregnancy could lead to problems in the development of the fetus, both structurally as in the case of morphogenesis, and in motor and cognitive development.

Onderzoeksproduct en/of interventie

SSRI

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Newborn child exposed to an SSRI in utero.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Newborn child exposed to a non-SSRI antidepressant in utero.
Newborn child exposed to anti-epileptic drugs in utero.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-04-2007
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-10-2006
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	NL730
NTR-old	NTR740
Ander register	: N/A
ISRCTN	ISRCTN53506435

Resultaten

Samenvatting resultaten

Planned: 4 manuscripts.
One manuscript each on: otcome after 1 week; after 3 months; after 2 years; after 6 years.