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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22808

Source
NTR

Brief title
SMOK

Health condition

The use of SSRI by pregnant women.

Sponsors and support

Primary sponsor: n.a.
Source(s) of monetary or material Support: n.a.

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Intervention

SSRI

Contacts

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Eligibility criteria

Inclusion criteria

Newborn child exposed to an SSRI in utero.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	15-04-2007
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion Date:	18-10-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL730
NTR-old	NTR740
Other	: N/A
ISRCTN	ISRCTN53506435

Study results

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