

SMOK-study: selective serotonin reuptake inhibitor medication in pregnant women - effect on development of children

Submission date 22/11/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/11/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/06/2013	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr C N van der Veere

Contact details
University Medical Centre Groningen (UMCG)
Beatrix Children's Hospital
P.O. Box 30001
Groningen
Netherlands
9700 RB
c.n.van.der.veere@bkk.umcg.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR740

Study information

Scientific Title

Acronym

SMOK

Study objectives

Regarding the facts that in the foetus 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 selective serotonin reuptake inhibitor (SSRI) in pregnancy could lead to problems in the development of the foetus, both structurally as in the case of morphogenesis, and in motor and cognitive development.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the "Medisch Ethische Toetsings Commissie (METc) of the UMCG (Universitair Medisch Centrum Groningen)" on the 22nd January 2007.

Study design

Multicentre, prospective case-controlled parallel group trial

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Health condition(s) or problem(s) studied

SSRI (selective serotonin reuptake inhibitor), pregnancy

Interventions

120 healthy newborn babies were examined, 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.

Added as of 29/05/2007:

This study officially started recruiting patients on the 15th April 2007. The initial anticipated start date of this trial was 30/11/2006.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Selective serotonin reuptake inhibitor

Primary outcome measure

1. In the first week after birth and at three months post-term: quality of general movements
2. At the age of 2 years and 6 years: motor and cognitive development

Secondary outcome measures

No secondary outcome measures

Overall study start date

15/04/2007

Completion date

30/11/2014

Eligibility**Key inclusion criteria**

Newborn child exposed to an SSRI in utero

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

120

Key exclusion criteria

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

Date of first enrolment

15/04/2007

Date of final enrolment

30/11/2014

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre Groningen (UMCG)

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Centre Groningen (UMCG) (The Netherlands)

Sponsor details

P.O. Box 30001

Groningen

Netherlands

9700 RB

Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl/azg/nl/english/azg/>

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre Groningen (UMCG) (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	28/05/2013		Yes	No