

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

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

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## 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?
<a href="#">Results article</a>	results	28/05/2013		Yes	No