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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/11/2006	**Overall study status** Completed	
Last Edited 28/06/2013	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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(s)
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

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/11/2014

Eligibility

Key inclusion criteria
Newborn child exposed to an SSRI in utero

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Groningen (UMCG) (The Netherlands)

Results and Publications

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