SSRI's during pregnancy and lactation. Individualized care with drug analysis: Measurements of antidepressants In the Neonate anD breast milk.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Neonatal and perinatal conditions
Study type	Observational invasive

Summary

ID

NL-OMON44977

Source
ToetsingOnline

Brief title
MIND study: Measurements of antidepressants In the Neonate anD breast milk

Condition

- Neonatal and perinatal conditions
- Psychiatric disorders NEC

Synonym
depression

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Nederlandse Vereniging van Klinische Farmacologie en Biofarmacie (NVKF&B)

Intervention

Keyword: drug levels, lactation, pregnancy, SSRI's

Outcome measures

Primary outcome

The relationship between SSRI drug levels and clinical effects after exposure

to SSRI*s during pregnancy and lactation in (pre)term infants.

Secondary outcome

The relationship between neonatal drug levels and long term developmental

outcome, the influence of co-medication and the relationship between NAP and

cortisol levels.

Study description

Background summary

The prevalence of antidepressant use during pregnancy in The Netherlands is 2-3% and concerns mainly selective serotonine reuptake inhibitors (SSRI*s). Approximately 30% of prenatally exposed neonates develop neonatal adaptation problems (NAP),), which are usually mild and self limiting. Currently, it is not clear which neonates are at risk to develop NAP and if there is a relation with the SSRI concentration in the blood of the neonate. Possible factors which can have an effect on NAP are for example gestational age, lactation and maternal co-medication (e.g. benzodiazepines). Although long term effects seem to be generally favourable, the relationship with neonatal drug levels is unknown. Also, there might be a relationship between NAP and stress in the neonate and therefore a relationship between neonatal cortisol levels and NAP.

Study objective

With this research project we will investigate the relationship between SSRI concentration in the (pre)term neonate and clinical short and long term effects on the neonate after exposure to SSRI*s during pregnancy and lactation. Furthermore, the influence of co-medication, as well as the relationship between NAP and cortisol will be investigated. We aim to optimize providing information to health care professionals and parents by analyzing the relationship between SSRI-concentrations and short and long term effects in the neonate.

Study design

This is a prospective observational cohort study of the most commonly used SSRI*s during pregnancy and lactation without any study related invasive interventions.

Study burden and risks

This observational study concerns an existing situation, namely exposure to SSRI*s during pregnancy and lactation. A maximum of 3 mL of blood will be obtained from the neonate, divided over 4 sampling moments, using the dried blood spot method. We tend to combine blood sampling with routine blood analysis if applicable. The risk associated with participation can be considered negligible and the burden can be considered minimal. Due to the nature of the study it is not feasible to conduct the research in another group than (pre)term infants.

Also saliva will be analysed at birth and at the age of 3 months and 1 year.

Currently, there is no standard follow up procedure for SSRI exposed infants. With respect to investigate the long term effects on children after exposure to SSRI*s during pregnancy and lactation, we will invite participating neonates for follow up at the age of 3 months, 1 and 2 years. Development will be investigated by a physiotherapist and at the age of 2 years also by a psychologist.

During pregnancy, blood will be obtained 1 times of the mother
During lactation, the mother will be asked to donate a small amount of breast milk 3 times for analysis. Also blood will be obtained at these moments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Exposure to SSRI*s in at least the last 4 weeks before delivery or exposure during lactation.
Written informed consent from the parents or a legal guardian.

Exclusion criteria

Syndromal or chromosomal abnormalities.
Congenital metabolic disease.
Severe hepatic and renal insufficiency.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	180
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-04-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL54238.029.16