Stop or Go?
Tapering antidepressants in pregnancy: A pragmatic multicenter RCT to investigate risk and benefits for mother and child.

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The aim of this study is to investigate the effect of guided tapering in early pregnancy as compared to continuation of SSRIs during pregnancy. We will study effects on both mother and child with a pragmatic approach.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44592

Source
ToetsingOnline

Brief title
Stop or Go?

Condition

- Other condition
- Maternal complications of pregnancy
- Mood disorders and disturbances NEC

Synonym
Depression, depressive disorder

Health condition

effecten op kind na de geboorte

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Antidepressants, Child development, Pregnancy, RCT

Outcome measures

Primary outcome

Risk of relapse of maternal depressive disorder (as defined by the Structured Clinical Interview for DSM disorders) during pregnancy and up to 3 months postnatal.

Secondary outcome

Mother:

- Time to relapse of depressive disorder up to 3 months after delivery.

- SSRI use and dosage, psychiatric co-medication (e.g. benzodiazepines), adherence to preventive cognitive therapy

- Side effects of (tapering of) medication (checklist)

- Hazardous behavior (e.g. use of alcohol/drugs, suicidality)

- Stress, depressive symptoms, anxiety and childhood trauma

- Direct medical costs (until 3 months postpartum), indirect costs (with adjustment for pregnancy leave period), quality of life effects mother

- Obstetric complications during pregnancy and delivery (spontaneous abortion, referral midwife to obstetrician, preeclampsia [ISSHP definition], assisted

delivery, induced labour for maternal indication [premature, term delivery],

epidural anaesthesia for pain, caesarean section)

Child:

- Specific: child condition at birth (poor neonatal adaptation defined as:

5-min Apgar <7 and/or admission to pediatric ward/NICU)

- General: gestational age at birth, birth weight, head circumference at birth;

these measures also expressed as deviance scores/percentiles

- Neuromotor development (General Movements [GM])

- Child behavior (Child Behaviour Check List at 18 months; parental and

caregiver report)

- Direct medical costs, quality of life (proxy)

- Information from CJG about child behaviour at 2 years

Study description

Background summary

About 2% of pregnant women in the Netherlands use Selective Serotonin Reuptake Inhibitors (SSRIs) during their pregnancy for symptoms of depression and/or anxiety. SSRI use in pregnancy is controversial. On the one hand SSRIs may be toxic to the intrauterine developing child, on the other hand, relapse of depression and/or anxiety during pregnancy holds risks for both mother and child. Among patients and professionals there is an urgent need for evidence from randomized studies to make rational decisions regarding continuation or tapering of SSRIs during pregnancy. No such studies exist to date.

Study objective

The aim of this study is to investigate the effect of guided tapering in early pregnancy as compared to continuation of SSRIs during pregnancy. We will study

effects on both mother and child with a pragmatic approach.

Study design

A pragmatic, multicenter, randomized controlled trial with a 1:1 allocation.

Intervention

1. Preventive cognitive therapy with guided tapering of SSRIs
2. Continuation of SSRIs

Study burden and risks

Burden is minimal and consist of repeated questionnaires, a blood withdrawal and a home visit 12 weeks after delivery. Both groups encounter the risk of depressive relaps.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

< 16 weeks pregnant
SSRI use for depressive symptoms

Exclusion criteria

Multiple pregnancies
Severe medical conditions
Current relapse of depression
Current other severe psychiatric disorders

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-01-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-08-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-11-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-02-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-03-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL50164.078.14