# Adherence of antidepressants during pregnancy

Published: 24-08-2009 Last updated: 04-05-2024

Observe the adherence rate of antidepressants during pregnancy and secondary exploration of possible factors which contribute to non-adherence

**Ethical review** Approved WMO **Status** Recruitment stopped

**Health condition type** Pregnancy, labour, delivery and postpartum conditions

**Study type** Observational non invasive

## **Summary**

#### ID

NL-OMON33081

#### Source

ToetsingOnline

#### **Brief title**

Adherence of antidepressants during pregnancy

#### **Condition**

- Pregnancy, labour, delivery and postpartum conditions
- Mood disorders and disturbances NEC

#### **Synonym**

non-compliance

#### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Isala Klinieken

Source(s) of monetary or material Support: de trialpot van de afd Klinische Farmacie

#### Intervention

**Keyword:** Adherence, antidepressants, pregnancy

#### **Outcome measures**

#### **Primary outcome**

Adherence rate of antidepressants during pregnancy

#### **Secondary outcome**

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# Study description

#### **Background summary**

Relapse of depression during pregnancy may be harmful for mother and foetus. A main risk factor for relapse is non-adherence of pharmacotherapy (antidepressants). Data about adherence of antidepressants during pregnancy are lacking. This observational study will focus on the adherence rate of antidepressants during pregnancy.

#### Study objective

Observe the adherence rate of antidepressants during pregnancy and secondary exploration of possible factors which contribute to non-adherence

#### Study design

All pregnant women with psychiatric morbidity may encounter the special program for this population in our hospital. Those women with antidepressants will be asked to participate in this observational study. During pregnancy as much as possible, within all trimesters the adherence rate will be measured by special MEMS-packages provided by the department of clinical pharmacy. Data from public pharmacies of refill rates will be used to determine inside base-line adherence rates. Adherence rate will be defined as a percentage of MEMS-openings and number of openings according to the doctor\*s prescription. Women will be asked for TDM monitoring and taking blood samples when antidepressants will be dispensed. Parameters of influence will be collected: age, height, weight, demographic parameters, and a standardised questionnaire (DAI, BMQ and for once an in-house developed questionaires about beliefs of antidepressants during

pregnancy.

## Study burden and risks

Not applicable. Blood withdrawal for TDM is part of normal treatment. Drug dispensing is a normal routine procedure.

## **Contacts**

#### **Public**

Isala Klinieken

Dr van Heesweg 2 8025 AB NL

**Scientific** 

Isala Klinieken

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## **Trial sites**

### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

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

## **Inclusion criteria**

Patients will be included if they are pregnant, use antidepressants, regardless pharmacological class, and signed informed consent.

#### **Exclusion criteria**

Incapacity to follow the study protocol according to the attending specialist.

# Study design

## **Design**

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

#### Recruitment

Generic name:

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2009

Enrollment: 50

Type: Anticipated

## Medical products/devices used

Product type: Medicine

Brand name: Anafranil

Registration: Yes - NL intended use

Clomipramine

Product type: Medicine

Brand name: Imipramine

Generic name: Imipramine

Registration: Yes - NL intended use

Product type: Medicine

Brand name: Lexapro

Generic name: escitalopram

Registration: Yes - NL intended use

Product type: Medicine

Brand name: Nortrilen

Generic name: Nortriptyline

Registration: Yes - NL intended use

Product type: Medicine
Brand name: Tryptizol

Generic name: Amitriptyline

Registration: Yes - NL intended use

# **Ethics review**

Approved WMO

Date: 24-08-2009

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

Approved WMO

Date: 29-04-2010

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

# **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

EudraCT EUCTR2009-011893-13-NL

CCMO NL27726.075.09