Adherence of antidepressants during pregnancy

Published: 24-08-2009
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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
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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

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
Generic name:	Clomipramine
Registration:	Yes - NL intended use
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