Persisting complaints after hypertensive complications in pregnancy and the effects on daily functioning

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1. To identify associations or an absence of associations between complaints and impaired daily functioning.2. To get an insight in events in pregnancy related to persistant complaints and impairments in daily functioning after pregnancy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Observational non invasive

Summary

ID

NL-OMON31823

Source
ToetsingOnline

Brief title
Persisiting complaints after PE / HELLP and daily functioning.

Condition

- Maternal complications of pregnancy

Synonym
Pre-eclampsia, toxic pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: functioning, HELLP, persistant, pre-eclampsia

Outcome measures

Primary outcome

Physical and mental symptoms or complaints and limitations in daily functioning

are dependent study parameters. Events in or results from (complicated)

pregnancy are in this study independent study parameters. The level of

limitation is the main outcome of this study.

Secondary outcome

Personality characteristics and character are parameters that can effect the

main outcome.

Study description

Background summary

Hypertensive complications during pregnancy (preeclampsia, eclampsia and the HELLP syndrome) are important causes of maternal and perinatal morbidity and mortality. In the academic hospital in Maastricht research is done to find relations between endothelial function, vesselcompliance, defence mechanisms and maternal tendency on one hand and the origin of hypertensive complications in pregnancy on the other hand. Recently some space has been created within this approach to complete medical service with more attention for mental and social consequences of hypertensively complicated pregnancies and for counseling of behaviour that increases risk conditions. In normal practice persisting symptoms are sometimes associated with limitations in daily functioning. To offer effective care it's important to choose the best interventions, to be able to anticipate on potential limitations based on symptoms and to consult correctly. This descriptive study is also meant to rubricate and quantify physical and mental symptoms, assuming a causality between these symptoms and limitations in daily functioning.

Hypothetically this means that women develop symptoms after a severe hypertensively complicated pregnancy wich seriously undermine functions within

family, household, work and hobbies. The following question is presented:

1. Are there associations in persistant complaints and impaired daily functioning in women after an hypertensive complicated pregnancy

Study objective

1. To identify associations or an absence of associations between complaints and impaired daily functioning.
2. To get an insight in events in pregnancy related to persistant complaints and impairments in daily functioning after pregnancy.

Study design

The study uses a quantitative design. Within the cohorts, the studygroup is compared with two control groups. A questionnaire is being sent to the selected respondents. During analysis confounders are being corrected.

Study burden and risks

Questionnaires are being sent to the respondents home adress. To fill in the questionairre takes about approximatily 15 minutes. The content of the questionnaire can be confronting or in some ways an emotional load, although earlier researchers experienced a that respondents felt good in filling in their emotions. The questionnaire measures complaints, symptoms and impairments in functioning. Respondents return the questionnaire anonymously.

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

Study group: para 1, after going trough a hypertensively complicated pregnancy; delivery has taken place maximally one year before the study; maximum duration of pregnancy: 32 weeks
Control group: para 1, after going trough an uncomplicated pregnancy; delivery has taken place maximally one year before the study; minimal duration of pregnancy: 38 weeks.

Exclusion criteria

Studygroup: mental, physical and social symptoms before the complicated pregnancy; current pregnancy.
Control group: mental, physical and social symptoms before the complicated pregnancy; current pregnancy; postnatal hospitalization of mother and child or postnatal mortality.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2008
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	20-02-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL20332.068.07