psychological consequences of pre-eclampsia

Published: 21-11-2012
Last updated: 26-04-2024

1. the primary objective of this study is to examen the incidence and prevalence of PTSDand depression in pre-eclampsia patients after delivery2. a secondary objective is to identify risk factors during pregnancy, durante partu and postpartum...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38136

Source
ToetsingOnline

Brief title
psychological consequences of pre-eclampsia

Condition

- Other condition
- Psychiatric and behavioural symptoms NEC
- Lifestyle issues

Synonym
preeclampsia, toxicose

Health condition

PTSD, depressie, angst stoornissen en lichamelijke klachten als gevolg hiervan.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: consequences, pre-eclampsia, psychological

Outcome measures

Primary outcome

PTSD incidence and prevalence

depression incidence and prevalence

Secondary outcome

quality of life as experienced

functional disability

physical complaints

outcome/health of the child

anxiety

acute stress

Study description

Background summary

Early-onset pre-eclampsia is a serious complication of pregnancy before 34 weeks of gestational age. It is defined as hypertension (not existing before) and proteinuria in the second half of the pregnancy. Late-onset pre-eclampsia

differs from early-onset pre-eclampsia by the onset, which is after 37 weeks of gestational age. The perinatal and maternal mortality and morbidity rates are considerably lower in late-onset pre-eclampsia. The pathophysiological changes in patients with pre-eclampsia such as vascular dysfunction, activation of the coagulation cascade and increased capillary permeability can be explained by a generalized inflammatory response resulting in endothelial dysfunction. Pre-eclampsia is a major cause of both perinatal and maternal morbidity and mortality.

While somatic disorders will disappear in approximately 3 months after delivery, the impact of psychological effects is much greater both for the mother and the father. The great amount of stress of the (acute) delivery, the disease itself and the worry about the premature born child can lead to psychological disorders like PTSD, depression, anxiety disorders and chronic physical complaints . Women with a history of pre-eclampsia have an increased risk for developing psychological problems such as PTSD shortly and in the late period after delivery.

Study objective

1. the primary objective of this study is to examen the incidence and prevalence of PTSDand depression in pre-eclampsia patients after delivery

2. a secondary objective is to identify risk factors during pregnancy, durante partu and postpartum predicting PTSD and depression in women who have a history of pre-eclampsia

The objective of this study is to determine the incidence of PTSD and PPD in preeclampsia patients in the first year postpartum, while taking into account addition risk factors related to PTSD or PPD in order to develop a prognostic model. This model is expected to be useful in clinical practice for the prediction of the development of PTSD or PPD at an early stage enabling the development of primary prevention.

Secondary objective
If these women with pre-eclampsia have an increased risk of developing psychiatric disorders this justifies primary/secundary prevention of PTSD, depression, anxiety disorders and physical complaints. Furthermore if these women have an increased risk for psychological problems than early signs of these problems could be evaluated early after delivery and treated if necessary.
This could be organised in a long term follow-up of women with pre-eclampsia in an multidisciplinairy outdoor patient department where patients are screened for risk factors for psychological disorders and treated if necessary. This could be performed in co-operation with several disciplines like internal

medicine, cardiology and psychology.

Study design

This proposed study is set up as an observational prospective cohort study and will be carried out in the Wilhelmina Children Hospital as part of the University Medical Centre in Utrecht. The duration of the study will be approximately 3-4 years.

Study burden and risks

The burden for the women is minimal and is restricted to 5 moments of 1 hour each for this study.

risk and burden is one step above "no risk ". so minimal exeding no risk is what we counted for this study. it's a non invasive study, but asking questions by interview and filling out questionnaires may exaggerate emotions and feelings can worry the women.
If this is the case the researchers and the social workers always are standby.

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

being 18 year's or older
be able to speak and understand well the Dutch language
diagnostic criterium preeclampsia or HELLP

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	215
Type:	Anticipated

Ethics review

Not approved

Date:	21-11-2012

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL31029.041.12