Cardiovascular disease in formerly preeclamptic women

Published: 08-04-2009
Last updated: 06-05-2024

Our primary objective is to compare the changes in renal vascular resistance in 10 years between women with a history of preeclampsia and controls.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of labour and delivery
Study type	Observational invasive

Summary

ID

NL-OMON33561

Source
ToetsingOnline

Brief title
Cardiovascular disease and preeclampsia

Condition

- Maternal complications of labour and delivery
- Vascular hypertensive disorders

Synonym
hypertensive disorders of pregnancy, Toxemia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiovascular disease, Hemodynamics, Preeclampsia, Renal function

Outcome measures

Primary outcome

Renal vascular resistance

Secondary outcome

Glomerular filtration rate (GFR), total peripheral vascular resistance (TPVR),

blood pressure, plasma volume, arterial and venous compliance and

cardiovascular morbidity.

Study description

Background summary

Preeclampsia is associated with an increased risk on the development of cardiovascular and renal disease. It seems that similar risk factors are both predictive for preeclampsia and cardiovascular disease. We hypothise that women with a history of preeclampsia have accelerated vascular aging in comparison with controls.

Study objective

Our primary objective is to compare the changes in renal vascular resistance in 10 years between women with a history of preeclampsia and controls.

Study design

Observational case-control study. A longitudinal study, based on a previous study in the period of 1996-1999.

Study burden and risks

The introduction of two intravenous catheters may be painfull. In total 60 ml of blood will be sampled. The infusion of the following solutes (para-aminohippo acid, inuline, HSA) will rarely give an allergic reaction.

Plasmavolume measurement is done by albumin tagged with radioactive iodine, which gives a low dose of radiation.

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

Inclusion of women who participated in a previous clinical study in the period of 1996-1999. Women with preeclampsia or HELLP syndrome in history and controls with a history of uncomplicated pregnancy.

Exclusion criteria

Preexistent hypertension (before pregnancy)

Study design

Design

Study type:	Observational 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):	04-09-2009
Enrollment:	30
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	08-04-2009
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
Other	5236 (NTR nummer volgt)
CCMO	NL26151.068.08