

# Frequency of visual field defects in formerly eclamptic women, a pilot study

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Vision disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON37060

### Source

ToetsingOnline

### Brief title

Visual field defects following eclampsia

## Condition

- Vision disorders
- Congenital and peripartum neurological conditions
- Maternal complications of pregnancy

### Synonym

convulsions, hypertension

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Junior Scientific Masterclass Groningen

## Intervention

**Keyword:** Cerebral white matter lesions, Eclampsia, Pregnancy, Visual field defects

## Outcome measures

### Primary outcome

The main study parameter is the prevalence of visual field defects in formerly eclamptic.

### Secondary outcome

The secondary study parameter is the score on the vision-related quality of life questionnaire of formerly eclamptic women and matched controls.

## Study description

### Background summary

Eclampsia is the occurrence of convulsions in a preeclamptic woman, which can not be attributed to another cause. Prodromal symptoms include headache, visual disturbances, nausea and altered mental state. Eclampsia is thought to be a form of posterior reversible encephalopathy syndrome (PRES), in which an acute increase in blood pressure exceeds the upper limit of cerebral autoregulation, leading to forced dilatation, blood-brain barrier disruption and cerebral edema formation. The reversibility of this syndrome has been questioned. In previous studies eclamptic women, as well as a number of severely preeclamptic women, showed persistent cerebral white matter lesions on MRI on both short and long term follow-up. The location of these lesions as found in PRES and eclampsia is mainly parieto-occipital. Therefore the most common visual abnormality during the acute phase of PRES is transient cortical blindness but homonymous hemianopsia, visual neglect, scotomata and blurred vision can also occur. In general eclamptic patients regain their vision, however, incidental permanent visual field abnormalities, in particular hemianopsia but also blindness, have been described to persist years after the acute phase. It might be possible that unconscious hemianopsia is present in a considerable number of the formerly eclamptic patients. Therefore, this study proposal entails the prevalence of visual field defects in formerly eclamptic women. Furthermore, vision-related quality of life is compared between formerly eclamptic and normotensive parous control subjects.

## Study objective

The primary objective of this pilot study is to assess the prevalence of visual field defects in formerly eclamptic women. The secondary objective is to compare the vision-related quality of life between formerly eclamptic and normotensive parous control subjects.

## Study design

Pilot study

## Study burden and risks

All participants will be asked to fill out a vision related quality of life questionnaire. In addition, formerly eclamptic women are asked to undergo visual field testing. In case of abnormal visual field testing, the test will be repeated once. In case of repeated abnormal visual field testing the participant will be referred for an ophthalmologic examination by an ophthalmologist to rule out glaucoma. There are no risks associated with participation. The burden mainly consists of the time it takes to undergo visual field testing and/or to fill out the questionnaire. The main benefit for formerly eclamptic women is the possible early detection of treatable ophthalmologic conditions.

## Contacts

### Public

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### Scientific

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## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

One group of women over 18 years old, who were diagnosed with eclampsia between 1988 and 2008.

Eclampsia is defined according to the definition by the International Society for the Study of Hypertension in Pregnancy.

One group of healthy parous controls who have been matched for age and year of index pregnancy to the formerly eclamptic group.

### Exclusion criteria

Glaucoma

Epilepsy or other neurologic disorders, including a known cerebrovascular accident, intracranial infections or a history of any neurosurgical procedure.

Pregnancy

## 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:	Other

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 06-10-2009  
Enrollment: 80  
Type: Actual

## Ethics review

Approved WMO  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL27489.042.09