The prevalence of brain white matter lesions after pregnancy and the relationship with neurocognitive functioning

Published: 23-01-2012 Last updated: 30-04-2024

The primary objective of this study is to determine the prevalence of white matter lesions and subjective/objective neurocognitive functioning in women several years after pregnancy compared to nulliparous women The secondary objective is to...

| Ethical review | Approved WMO |
|-----------------------|---|
| Status | Recruitment stopped |
| Health condition type | Central nervous system vascular disorders |
| Study type | Observational invasive |

Summary

ID

NL-OMON37705

Source ToetsingOnline

Brief title

Brain white matter lesions and neurocognitive function after pregnancy

Condition

- Central nervous system vascular disorders
- Pregnancy, labour, delivery and postpartum conditions
- Cognitive and attention disorders and disturbances

Synonym

cognition, Pregnancy

Research involving

Human

1 - The prevalence of brain white matter lesions after pregnancy and the relationshi ... 22-06-2025

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, Neurocognitive functioning, Pregnancy

Outcome measures

Primary outcome

The main study parameter is the prevalence of white matter lesions assessed by

MRI using a 3 Tesla MRI.

Secondary outcome

Secundary study parameters are:

Scores on the questionnaires: cognitive failures questionnaire (CFQ), hospital

anxiety and depression questionnaire (HADS), Utrechtse coping lijst (UCL).

Scores on neurocognitive tests:

- Nederlandse Leestest voor Volwassenen (NLV)
- Wechsler Adult Intelligence Scale (WAIS) III letter-number sequencing and

digit span, digit-symbol coding, symbol search

- Corsi Block-Tapping Task
- 15-Word Learning test
- Location Learning test
- Grooved Pegboard
- Groningen Intelligence Test (GIT) II figure exploration

- Delis-Kaplan Executive Function System (D-KEFS) Trail Making test, Tower test
- STROOP Color Word test
- Verbal Fluency test
- Figure Fluency test
- Amsterdam Short-Term Memory (ASTM) test

Study description

Background summary

The incidence of brain white matter lesions (WML) in the longterm in formerly (pre-)eclamptic women and women who had a normotensive pregnancy has recently been investigated by our group. Neuroimaging (MRI) of women who experienced eclampsia on average 7 years prior revealed WML*s in 41 %, following preeclampsia this was 37 %, whereas women who experienced normotensive pregnancies demonstrated WML*s in 21 % of the cases. Therefore, the exact clinical importance of the presence of WML in this relatively young cohort (average age 40 years) is unclear. The question arises whether these lesions are a result 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. Another possibility is that they represent a risk marker for future cardio/cerebrovascular disease. White matter lesions (WML) are a frequent finding on T2-weighted MRI of the brain in elderly individuals, but their prevalence and severity in younger asymptomatic populations is less well studied. These lesions are seen commonly in individuals in their 50s and 60s, especially those with risk factors for small vessel disease such as hypertension and diabetes. There is evidence that the presence and particularly, the severity of WML are important risk factors for the development of cognitive impairment, vascular dementia, Alzheimer*s disease and stroke. In their 40s a significant number of otherwise healthy individuals have small lesions, although the reported prevalence range is large (6-50%). Pregnant women frequently report forgetfulness during pregnancy, but also in the postpartum period. How long into the postpartum period these problems persist is not clear. To our knowledge, no studies have been performed in women several years after pregnancy compared to women who have never been pregnant. The examination of WMLs and their neurocognitive sequelae in younger individuals is important for a variety of reasons. If the pathogenesis of these lesions is to be understood and potentially modifiable factors identified, then the study of individuals in the earliest stages of development of the lesions

would be valuable. Moreover, the functional consequences of these lesions in mid-life are of interest as many noncognitive neuropsychiatric syndromes have been related to the lesions.

Study objective

The primary objective of this study is to determine the prevalence of white matter lesions and subjective/objective neurocognitive functioning in women several years after pregnancy compared to nulliparous women The secondary objective is to determine the effect of educational level, employment, marital status, age, cerebrovascular risk factors and anxiety and depression on outcomes of questionnaires, neurocognitive tests and white matter lesions

Study design

The proposed project is a retrospective cohort study, which will be performed at the Department of Obstetrics and Gynecology of the University Medical Center Groningen. The duration of this study will be approximately one year.

Study burden and risks

There are no risks from participation in this study. The extent of the burden mainly exists of the time needed to make the MRI scan, do the neurocognitive testen and fill out the questionnaires.

Contacts

Public Universitair Medisch Centrum Groningen

Hanzeplein 1, postbus 30001 9700 RB Groningen NL **Scientific** Universitair Medisch Centrum Groningen

Hanzeplein 1, postbus 30001 9700 RB Groningen NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

One group of women who were never pregnant will be included in this study. Women will be recruited by means of an invitation which will be spread in local newspapers and on the internet. Women can reply to this invitation. From the repliers, 62 women will be matched for age and level of education with a healthy parous woman from a previous study.

Exclusion criteria

- Any pregnancy of more than 12 weeks gestation or current pregnancy
- Epilepsy or other neurologic disorder
- Pregnancy
- General MRI contraindications or claustrophobia
- Known cerebrovascular disease
- History of alcohol or substance abuse requiring therapy
- Insufficient comprehension of Dutch language
- Fertility treatment or diagnostic procedures

Study design

Design

| Study type: | Observational invasive |
|---------------------|---------------------------------|
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |

5 - The prevalence of brain white matter lesions after pregnancy and the relationshi ... 22-06-2025

| Masking: | Open (masking not used) |
|------------------|-------------------------|
| Control: | Active |
| Primary purpose: | Other |

Recruitment

М

| Recruitment status: | Recruitment stopped |
|---------------------------|---------------------|
| Start date (anticipated): | 24-02-2012 |
| Enrollment: | 62 |
| Туре: | Actual |

Ethics review

| Approved WMO | |
|--------------------|---|
| Date: | 23-01-2012 |
| 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 CCMO **ID** NL38044.042.11