The PERFORM study: Pre-Eclampsia and other Risk FactORs in relation to Migraine

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24250

Source
NTR

Brief title
PERFORM study

Health condition

Migraine, pre-eclampsia

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: The study will be funded by the principal investigator(s)

Intervention

Outcome measures

Primary outcome

The one-year (period) prevalence and incidence of migraine (both, migraine with aura and migraine without aura) among postpartum women who suffered from hypertensive disorders

in pregnancy compared to the one-year (period) prevalence and incidence of migraine in (healthy) women – relative to prior pregnancy.

Secondary outcome

1. Trends (and changes) in migraine frequency and severity over time before, during and after pregnancy in women who suffered from severe pre-eclampsia compared to (healthy) women with an uncomplicated labor until one-year postpartum.
2. The (possible) association between cognitive functioning/impairment within the first year postpartum and hypertensive disorders as well as migraine.
3. Correlations between migraine prevalence, incidence and severity and the cardiovascular risk factors in women who have suffered from severe pre-eclampsia during pregnancy until one-year postpartum.
4. The impact of migraine and pre-eclampsia onset and trends on the mental wellbeing.

Study description

Background summary

The Pre-Eclampsia and other Risk FactORs in relation to Migraine (PERFORM) study has a multidisciplinary approach to examine the relationship between migraine and hypertensive disorders in pregnancy, including (severe) pre-eclampsia in postpartum women (3 and 12 months after pregnancy). Indeed, both diseases, migraine and pre-eclampsia, are associated with cardiovascular risk factors, including blood pressure, serum total and high-density lipoprotein cholesterol, as well as endothelial dysfunction. We will study the one-year prevalence and incidence of migraine in postpartum women suffering from hypertensive disorders in pregnancy, including (severe) pre-eclampsia, which will be compared to a well-defined control group. Also, we will examine the impact of both migraine and pre-eclampsia on depression (severity), sleep, and the Quality of Life. This might elucidate the combined (additive or synergistic) effect of migraine and pre-eclampsia on depression, sleep, and/or Quality of Life. As data on cardiovascular risk factors are obtained in patients who suffered from severe pre-eclampsia, in our study a direct link between the course (onset) of migraine and cardiovascular risk profile in patients with pre-eclampsia can be drawn. Moreover, the prospective nature of the PERFORM study could elucidate the temporal relationship between both migraine and pre-eclampsia, as the date of migraine onset after pregnancy is clearly determined, mainly in patients who never had migraine in the past and who newly develop migraine one-year postpartum. Besides, within the PERFORM study we will measure cognitive performance prospectively in a subset of the included women.

Study objective

Pre-eclampsia is associated with migraine, probably due to a shared pathophysiological mechanism (endothelial dysfunction) and a cognitive decline postpartum.

Study design

Primary and secondary endpoints will be assessed after inclusion (at baseline), three and twelve months postpartum in both group 1 and 2. Validated questionnaires (on migraine, sleep, quality of life, depression, et cetera) and validated cognitive tests will be used to reach these endpoints.

Contacts

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Eligibility criteria

Inclusion criteria

Postpartum normotensive women or women with uncomplicated preexisting hypertension (group 1):
- Postpartum female adults aged ≥18 years;
- Women should either be normotensive or suffer from uncomplicated preexisting hypertension;
- Capable of understanding the purpose of the study, fully informed and given written informed consent (signed Informed Consent Form has been obtained).

A subset of group 1 will be asked to participate in the second part of the PERFORM study, which comprises the objective and subjective assessment of cognitive functioning and decline at the Erasmus MC. This subset of participants should include women who have had an uncomplicated and natural, non-assisted vaginal delivery (with a healthy baby born between 37 and 41 weeks). These women should also have had no complications during pregnancy and delivery, including hypertension or ruptures, which might have affected their mental state.

Postpartum women with (severe) pre-eclampsia, gestational hypertension, or superimposed

hypertension/pre-eclampsia (group 2):
- Postpartum female adults aged ≥18 years;
- Postpartum women who have experienced a severe form of pre-eclampsia during pregnancy, or gestational hypertension, or superimposed hypertension/pre-eclampsia;
- Capable of understanding the purpose of the study, fully informed and given written informed consent (signed Informed Consent Form has been obtained).

All subjects of group 2 will be asked to participate in the second part of the PERFORM study, which comprises of the objective and subjective assessment of cognitive functioning and decline.

Exclusion criteria

A (new) pregnancy within the first year after inclusion for the PERFOM study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-03-2021
Enrollment:	600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-05-2021
Application type:	First submission

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
NTR-new	NL9483
Other	METC EMC : MEC-2020-0658

Study results