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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24250

Bron
NTR

Verkorte titel
PERFORM study

Aandoening

Migraine, pre-eclampsia

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: The study will be funded by the principal investigator(s)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-03-2021
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	12-05-2021

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9483
Ander register	METC EMC : MEC-2020-0658

Resultaten