Potential effect of proton-pump inhibitor on angiogenic markers in preeclampsia

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PPI administration to women with confirmed PE lowers sFlt-1 levels and which may lead to less complications or progression of disease.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22488

Bron
Nationaal Trial Register

Verkorte titel
PPI Study

Aandoening

Preeclampsia

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference in sFlt-1 levels in women who have received PPI, in comparison to women who have not received PPI.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Preeclampsia (PE) is a devastating complication of pregnancy. The pathogenesis of PE is unknown. Recent data suggest an angiogenic imbalance characterized by elevated placenta-derived soluble Fms-like tyrosine kinase-1 (sFlt-1) and decreased placental growth factor (PlGF) levels in the maternal circulation. As a consequence, novel therapies now focus on sFlt-1 removal or PlGF supplementation. Given the fact that heme-oxygenase-1 negatively regulates sFlt-1 secretion, a role for proton pump inhibitors (PPIs) that upregulate heme oxygenase-1, has been suggested as potential treatment for preeclampsia. Indeed, Onda et al. observed that PPIs decreased sFlt-1 secretion from trophoblasts and reduced blood pressure in a transgenic PE mouse model with placental sFlt-1 overexpression. Recently, we reported that women with suspected/confirmed PE using PPIs, displayed lower levels of sFlt-1 in comparison to women not using PPIs.
In this study, our aim is to evaluate the potential effect of PPI administration in women with confirmed preeclampsia on sFlt-1 levels until delivery. Study design will be a single-centre, randomized, intervention proof-of-concept study performed at the Erasmus MC Rotterdam. Study population will consist of women with confirmed PE with a gestational age ≥ 20 weeks and <35 weeks who did not use PPIs at study entrance.
The intervention group will receive omeprazole, 40mg, once daily while the control group will receive no medication. In both groups, blood will be drawn at several time points, until delivery.

Doel van het onderzoek

PPI administration to women with confirmed PE lowers sFlt-1 levels and which may lead to less complications or progression of disease.

Onderzoeksopzet

Measurements of sFlt-1 will be performed on day 0 (before PPI use), 1, 2, 4, 8 and thereafter twice weekly until delivery

Onderzoeksproduct en/of interventie

Omeprazole 40mg once daily

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women (≥18 years) with a singleton pregnancy diagnosed with PE with a gestational age of ≥ 20 weeks and <35 weeks admitted to the obstetric department who give written informed consent, will be included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Multiple pregnancies
- Not willing to give written informed consent.
- Other reasons than (suspected) PE requiring hospitalization
- The use of PPI at time of randomization
- Contraindications or hypersensitivity to PPI use
- The use of medication affected by PPI
- Fetal death at time of inclusion
- Signs of fetal distress at time of inclusion
- Expected delivery of ≤ 2 days

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-12-2018
Aantal proefpersonen:	44
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	07-05-2019
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	NL7718
Ander register	METC EMC : MEC2018-078

Resultaten