PREdiction of Preeclampsia and AdveRse Events

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The sFlt-1/PlGF ratio test will have a false negative value in less than 5% of patients

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

Samenvatting

ID

NL-OMON29231

Bron
NTR

Verkorte titel
PREPARE

Aandoening

Pre-eclampsia, HELLP syndrome

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The objective is to assess the value of a sFlt-1/PlGF ratio in the classification and treatment of patients with (suspected) preeclampsia. Therefore, we will assess the false-negative rate when predicting the absence of preeclampsia within one week as the primary objective. Thereby, safety and efficacy analysis will include the potential influence of the test on clinical

decision making (i.e. hospitalization, home-monitoring or discharge).

Toelichting onderzoek

Achtergrond van het onderzoek

Currently, preeclampsia is diagnosed by elevated blood pressure and protein excretion in 24-hour urine (the “gold standard”). However, the specificity and reliability of these separate assessments to predict who will develop preeclampsia, eclampsia, or hemolysis, elevated liver enzymes an low platelet count (HELLP) syndrome is poor. As a consequence, women with signs and symptoms associated with preeclampsia may be unnecessarily hospitalized for intensive monitoring until preeclampsia is ruled out which consequentially leads to high costs.
An imbalance of (anti)angiogenic factors, including soluble fms-like tyrosine kinase-1 (sFlt-1) and placental growth factor (PlGF), has been found in women with preeclampsia. In recent studies, the determination of these biomarkers in pregnant women has shown potential value for diagnosing and predicting preeclampsia. Predicting the absence of preeclampsia in patients with suspicion of the disease may lead to a reduction in over-diagnosis, admission, over-treatment and lower the costs. In England, Germany and Austria the Elecsys sFlt-1/PlGF ratio test is already used in daily clinical practice and the test is included in their national protocols. In the Netherlands, patients with suspected preeclampsia can be either hospitalized or allocated to the home-monitoring program. The adding of the sFlt-1/PlGF ratio test to daily clinical practice could contribute to adequate decision making in the Dutch obstetrical care system.
The present study intends to assess the value of a sFlt-1/PlGF ratio in the classification and treatment of patients with (suspected) preeclampsia in the Dutch obstetrical care system. The ultimate goal is to introduce a novel clinical prediction rule, to reduce the need for hospitalization and rule out preeclampsia in a higher proportion of patients without compromising safety.

Doel van het onderzoek

The sFlt-1/PlGF ratio test will have a false negative value in less than 5% of patients

Onderzoeksopzet

Patients will be enrolled till a sample size of approximately 400 is achieved.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects enrolled in the study must meet the following inclusion criteria:
1) Age ≥ 16 years
2) Gestational age of from 20 weeks and 0 days
3) Signed written informed consent
4) a. Suspected preeclampsia as a protocol defined definition stated in Appendix Table 2
OR
b. Confirmed preeclampsia as defined by the International Society for the Study of Hypertension in Pregnancy (ISSHP)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects will be excluded from participation if they meet any of the following exclusion criteria:
1) Insufficient understanding of Dutch language

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	26-12-2017
Aantal proefpersonen:	400
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-11-2019
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	NL8308
Ander register	METC LUMC : P17.168

Resultaten