The PreRisk calculator in suspected or confirmed preeclampsia: A new tool to safely reduce the number of unnecessary admissions’

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Application of the PreRisk calculator (based on the sFlt-1/PlGF ratio, protein-to-creatinine ratio and gestational age) in patients with (suspected) PE can reduce the number and duration of hospital admissions without compromising maternal and fetal...

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

Samenvatting

ID

NL-OMON22891

Bron
NTR

Verkorte titel
The PreRisk Study

Aandoening

Preeclampsia

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1) Composite outcome of PE-related complications in both study arms: a. maternal complications defined as: acute renal failure, cerebral haemorrhage/oedema or infarction, death, eclampsia, development of the (partial) HELLP syndrome, pulmonary oedema, subcapsular liver hematoma, placental abruption, serious visual disturbances and
b. fetal complications defined as: fetal death and fetal distress requiring immediate delivery
2) Number and total duration of admissions.

Toelichting onderzoek

Achtergrond van het onderzoek

Preeclampsia (PE) is a syndrome most commonly defined as new onset hypertension and proteinuria at gestational week 20 or after, but the use of these variables to predict the course of PE and the development of adverse maternal and fetal/neonatal outcomes is not reliable. For reasons of safety, common practice today is that all patients suspected of PE are hospitalized for clinical and laboratory evaluation. A significant amount of research has been done on the ability of the sFlt-1/PlGF ratio to predict the absence or presence of PE or pregnancy-related complications and cutoff values to rule out or rule in PE or its course, have been provided. Recently, we reported from data of the PreRatio population that these predictions could be significantly improved by using continuous instead of dichotomous values of the biomarkers or their ratio and based on this knowledge, using multivariate regression analysis, we developed a risk-calculator (The PreRisk calculator) that includes the sFlt-1/PlGF ratio, gestational age and protein-to-creatinine ratio (manuscript in preparation). We hypothesize that the PreRisk calculator will help gynecologists better predict which patients are at high risk of serious maternal, fetal and neonatal preeclampsia-related complications and should be admitted to the obstetric ward and which patients can continue monitoring at home.
The aim of this study is to investigate whether application of the PreRisk calculator, based on the sFlt1/PlGF ratio, protein-to-creatinine ratio and gestational age in patients with suspected or confirmed PE leads to a decrease in the number and duration of hospitalizations to the obstetric ward and a reduction in costs while simultaneously not compromising maternal and fetal/neonatal health outcomes. Study design will be a nationwide multicenter non-inferiority randomized controlled trial (RCT) with a cost-effectiveness analysis. Study population will consist of patients with singleton pregnancies with suspected or confirmed PE with a gestational age between 20 and 37 weeks. In the intervention group the risk of maternal/fetal complications will be calculated using the PreRisk calculator and management decisions are adjusted accordingly: at a risk score <5.0% of maternal and fetal complications within the forthcoming 7 days patients will be followed at the outpatient clinic, while at a risk score ≥5,0% patients will be hospitalized. In the control group, decisions will be based on gynaecologist's clinical decision making.

Doel van het onderzoek

Application of the PreRisk calculator (based on the sFlt-1/PlGF ratio, protein-to-creatinine ratio and gestational age) in patients with (suspected) PE can reduce the number and duration of hospital admissions without compromising maternal and fetal health.

Onderzoeksopzet

Patients are recruited between 20 and 37 weeks, and will be part of the study until delivery.

Onderzoeksproduct en/of interventie

PreRisk calculator

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Women with a singleton pregnancy
- Age ≥ 18 years
- Gestational age ≥ 20 weeks and <37 weeks
- Suspected or confirmed PE

• Alive fetus without fetal distress requiring immediate delivery

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Other reasons than (suspected) PE requiring hospitalization.
- The presence of partial (HELLP) syndrome at time of inclusion.
- The presence of fetal death at time of inclusion.
- Pregnancy with a fetus affected by major congenital birth defects and/or chromosomal abnormalities
- Unable to provide written informed consent.

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:	15-06-2019
Aantal proefpersonen:	864
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	08-05-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48687
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7720
CCMO	NL63386.078.17
OMON	NL-OMON48687

Resultaten