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

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON48687

Source
ToetsingOnline

Brief title
The PreRisk study

Condition

- Maternal complications of pregnancy
- Vascular hypertensive disorders

Synonym
Toxemia of pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Kits voor sFlt-1 en PlGF worden gedoneerd door de firma Roche

Intervention

Keyword: Prediction model, preeclampsia, risk calculation, sFlt-1/PlGF

Outcome measures

Primary outcome

1) Difference in PE-related (maternal/fetal) complications between the

intervention group and control group.

2) Number and total duration of admissions.

Secondary outcome

Secondary outcomes:

- Number of outpatient clinic visits.

- Societal costs (health care and non-health care costs).

- Impact on psychological issues will be assessed by measuring anxiety with the

State-Trait Anxiety Inventory (STAI)

questionnaire. Questionnaires will be provided to women (and their partners)

whom have entered the trial at baseline, 1 week

after inclusion, and 1 week after delivery. Furthermore, qualitative interviews

in a subset of women and their partners will be

held.

- Neonatal complications (defined as: preterm delivery, admission to neonatal intensive care, artificial ventilation,bronchopulmonary dysplasia, infant respiratory distress syndrome, necrotizing enterocolitis, small-for-gestational age, cerebral bleeding/palsy and neonatal death)(13).

- Gestational age at delivery, prolongation of pregnancy duration since inclusion.

- Method of delivery and number of induced deliveries.

- Acceptability: Physician*s appreciation of the use of the risk calculator (PreRisk questionnaire twice a year). Qualitative interviews in a subset of physicians.

Study description

Background summary

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 obstretic ward and which patients can continue monitoring at home.

Study objective

The objective of our 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) PE can reduce the number and duration of hospital
admissions leading to a reduction of costs, without compromising maternal and fetal health.

Study design

Prospective, randomized, multicenter intervention study.

Intervention

Women with suspected or confirmed PE will be randomized into two groups:
- The usual care group will receive no intervention. This means that the management of these patients will be based on the gynaecologist*s clinical and on laboratory assessment. Blood samples will be collected weekly for the sFlt-1/PlGF ratio and risk calculation, which will be determined after the study.
- In the intervention group the serum biomarkers sFlt-1 and PlGF in addition to routine clinical and laboratory assessment will be determined at weekly intervals and with the use of the PreRisk calculator the chance of maternal/neonatal complications are calculated. As agreed with the gynecologists of the project group, patients with a score <5% do not require hospitalization and can be followed biweekly at the outpatient clinic.

Study burden and risks

The potential risks associated with the intervention group will be only for the patients who are sent home based on the PreRisk calculator. Although our hypothesis suggests that the PreRisk calculator could calculate which patients have a low risk of complications correctly, there is still a chance these patients could develop complications at home. To minimize this, these patients are seen once to twice weekly at the outpatient clinic, and the risk will be calculated weekly. Furthermore, gynecologists are allowed to treat a patient according to their own findings and clinician*s expertise, and not only based on the risk calculator.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230 's Gravendijkwal 230
Rotterdam 3000CA
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230 's Gravendijkwal 230
Rotterdam 3000CA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women (>=18 years) with (suspected) PE with a singleton pregnancy and a gestational age of >= 20 weeks and <37 weeks.
PE defined as de novo onset hypertension (systolic blood pressure of >=140 and diastolic blood pressure of >=90mm Hg) and proteinuria (protein-to-creatinine ratio >=30mg/mmol or >= 300mg/24h, or 2+ dipstick) at or after 20 weeks of pregnancy.

Exclusion criteria

Multiple pregnancies
Not willing to give written informed consent.

Other reasons than (suspected) PE requiring hospitalization
The presence of HELLP syndrome at time of inclusion
Fetal death at time of inclusion.
Pregnancy with a fetus affected by major congenital birth defects and/or chromosomal abnormalities

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-08-2019
Enrollment:	864
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-06-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	02-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22891
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63386.078.17
OMON	NL-OMON22891