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…

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22891

Source
NTR

Brief title
The PreRisk Study

Health condition

Preeclampsia

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- 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.

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 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.

Study objective

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.

Study design

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

Intervention

PreRisk calculator

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2019
Enrollment:	864
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	08-05-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48687
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results