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PRETECH: a new point-of-care blood test to detect preeclampsia early and improve pregnancy care

Submission date
10/02/2025

Recruitment status
No longer recruiting

Registration date
18/02/2025

Overall study status
Completed

Last Edited
18/02/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Preeclampsia (PE) is a serious complication of pregnancy characterized by hypertension after 20 weeks of gestation combined with one or more of the following: proteinuria, neurological complications, pulmonary edema, hematological complications, acute kidney injury, liver involvement, uteroplacental dysfunction. Preeclampsia occurs in approx. 3,5 % of pregnancies and is still one of the leading causes of fetal and maternal morbidity and mortality worldwide.
Preeclampsia appears to be triggered by the release and imbalance of growth factors from the placenta that leads to vessel dysfunction. In particular, serum levels of PlGF (placental growth factor) and sFlt-1 (soluble fms-like tyrosine kinase-1, also known as soluble VEGF receptor-1) are altered in women with preeclampsia. Circulating levels of PlGF and sFlt-1 have been shown to be able to discriminate normal pregnancy from preeclampsia even before symptoms occur. In women who develop preeclampsia, sFlt-1 levels have been found to be higher and PlGF levels have been found to be lower than in normal pregnancy.
The ratio of sFlt1 to PlGF has been shown to be a better predictor of preeclampsia than either measure alone. The sFlt1/PlGF ratio seems a reliable tool in particular to exclude the development and preeclampsia associated complications for the coming weeks.
This study aims at evaluating a rapid diagnostic test for the sFlt-1/PlGF ratio for the use at the point-of-care. The MOMM Diagnostics préXclude Alpha is a single-use electrochemical Enzyme-Linked Lateral Flow ImmunoAssay (ELLFIA) for the determination of the concentration of sFlt-1 and PlGF in 20 µL whole blood from fingerstick. It is used in combination with the eFlow Reader. Total duration of the test: 25 minutes.
Being able to identify or rule-out preeclampsia with the aid of a rapid diagnostic test during patient consultation may have a tremendous advantage for efficient patient management.

Who can participate?
Pregnant women over 18 years old with a gestational age of > 11+0 weeks.

What does the study involve?
Women who meet all inclusion criteria, agree to participate in the study and sign informed consent will have the following blood samples collected at enrollment:

1. A whole blood sample from a fingerstick (Specimen A)
2. A plasma sample from venipuncture using EDTA tubes (Specimen B)
3. A serum sample from venipuncture (Specimen C)
Specimens A and Specimens B will be immediately tested on site using the préXclude Alpha test for determination of sFlt-1 and PlGF levels.
Specimens C will be stored frozen (-20°C) and later tested by the reference lab as a batch within acceptable handling and storage conditions, as determined by the referenced sFlt-1 and PlGF assays.

What are the possible benefits and risks of participating?
Results from specimen analysis as well as the clinical information collected are not used for patient management decisions, except when they are part of the usual routine clinical care of patients.
The results of the study will be important for future patients at risk for preeclampsia. The study will help MOMM Diagnostics to develop a marketable rapid preeclampsia test to simplify the risk assessment of preeclampsia and patient management in the future.
The blood draws from venipuncture for this study will be included in other routine blood draws, such that there is no additional puncture.

Where is the study run from?
MOMM Diagnostics GmbH (Switzerland)

When is the study starting and how long is it expected to run for?
April 2024 to March 2026

Who is funding the study?
MOMM Diagnostics GmbH, Basel & Kantonsspital Baden, Clinical Trial Unit (Switzerland)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2024-01490

Study information

Scientific Title
Preeclampsia Test for Efficient Clinical Handling

Acronym
PRETECH

Study objectives
Preeclampsia (PE) is a serious complication of pregnancy characterized by de novo hypertension after 20 weeks of gestation combined with one or more of the following: proteinuria, neurological complications, pulmonary edema, hematological complications, acute kidney injury,

liver involvement, uteroplacental dysfunction. Preeclampsia occurs in approx. 3,5 % of pregnancies and results in substantial maternal and fetal or neonatal mortality and morbidity, often due to preterm delivery. Clinical manifestations can vary from mild to severe forms and early-onset (<34 weeks of gestation) vs. late-onset (>34 weeks of gestation); preeclampsia is still one of the leading causes of fetal and maternal morbidity and mortality worldwide.

Preeclampsia appears to be triggered by the release and imbalance of angiogenic and anti-angiogenic factors from the placenta that leads to endothelial dysfunction. In particular, serum levels of PlGF (placental growth factor) and sFlt-1 (soluble fms-like tyrosine kinase-1, also known as soluble VEGF receptor-1) are altered in women with preeclampsia. Circulating levels of PlGF and sFlt-1 have been shown to be able to discriminate normal pregnancy from preeclampsia even before clinical symptoms occur. In normal pregnancy, the proangiogenic factor PlGF increases during the first two trimesters and decreases as pregnancy progresses to term. In contrast, levels of the anti-angiogenic factor sFlt-1 remain stable during the early and middle stages of gestation and increase steadily until term. In women who develop preeclampsia, sFlt-1 levels have been found to be higher and PlGF levels have been found to be lower than in normal pregnancy.
The ratio of sFlt1 to PlGF has been shown to be a better predictor of preeclampsia than either measure alone. The sFlt1/PlGF ratio seems a reliable tool in particular to exclude the development and preeclampsia associated complications for the coming weeks. In addition, sFlt1 /PlGF has potential relevance as a prognostic parameter in PE and may be useful in prediction of preeclampsia and related maternal and fetal adverse outcomes, risk stratification and management.

In patients with signs and symptoms of preeclampsia, the sFlt1/PlGF ratio has been proven helpful in the short-term prediction of the disease. The sFlt1/PlGF ratio can also improve the prediction of early-onset preeclampsia for women with risk factors (including: history of intrauterine growth restriction (IUGR); preeclampsia; eclampsia; hemolysis, elevated liver enzymes and low platelet count (HELLP) syndrome; pre-gestational diabetes; abnormal uterine artery Doppler ultrasound). In unselected nulliparous women with a singleton pregnancy, screening with the sFlt1/PlGF ratio at ≈ 20, ≈ 28, and ≈ 36 gestational weeks has been proven to provide clinically useful prediction of the risk of the most important manifestations of preeclampsia (at 36 gestational weeks, an sFlt-1/PlGF ratio ≤ 38 had a negative predictive value for severe preeclampsia of more than 99 %).

This study aims at evaluating a rapid diagnostic test for the sFlt-1/PlGF ratio for the use at the point-of-care. The MOMM Diagnostics préXclude Alpha is a single-use electrochemical Enzyme-Linked Lateral Flow ImmunoAssay (ELLFIA) for the determination of the concentration of sFlt-1 and PlGF in 20 µL whole blood from fingerstick. It is used in combination with the eFlow Reader. Total duration of the test: 25 minutes.

The MOMM Diagnostics eFlow Reader is a portable electrochemical instrument used to measure the results of tests manufactured by MOMM Diagnostics. The eFlow Reader can be used in a laboratory or in a point-of-care setting. The eFlow Reader measures the voltage signals generated by the test cartridge that has been inserted in the reader. The signals are generated by local changes in oxidation-reduction potential based on an enzyme-linked lateral flow immunoassay running in the test cartridge. The higher the voltage (signal amplitude) and the faster the signal change (rate), the higher the analyte concentration.
Being able to identify or rule-out preeclampsia with the aid of a rapid diagnostic test during patient consultation may have a tremendous advantage for efficient patient management.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 28/04/2024, Ethikkommission Nordwest- und Zentralschweiz (Tellplatz 11, Basel, 4053, Switzerland; +41 61 268 13 50; eknz@bs.ch), ref: 2024-01490

Study design
Prospective single center blinded non-interventional study

Primary study design
Observational

Study type(s)
Diagnostic, Prevention, Screening, Efficacy

Health condition(s) or problem(s) studied
Preeclampsia

Interventions
One enrolment consists of two blood samples (capillary from the finger and venous) taken from the participant during a routine pregnancy check-up at the Kantonsspital Baden hospital. This is where the observation ends. A participant may be re-enrolled up to two times depending on the pregnancy trimester (e.g. giving two blood samples at 12, 20 and 36 weeks of gestation). Regarding the follow up, we would like to extend it to the delivery outcome to find out, whether the participants have developed preeclampsia or delivered an IUGR (intrauterine growth restriction) baby.

Intervention Type
Other

Primary outcome(s)
Assay test results from Specimens A (whole blood from a fingerstick), B (EDTA tube), and C (serum) from venous blood sampling at 12, 20 and 36 weeks of gestation

Key secondary outcome(s))
Usability of préXclude Alpha measured using feedback from the investigative staff on the usability of the préXclude Alpha test throughout the study

Completion date
01/03/2026

Eligibility

Key inclusion criteria
1. Signed informed consent
2. Pregnant woman ≥ 18 years of age
3. Gestational age > 11 weeks +0 days

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
Patients who have received heparin within 24 hours of enrolment.

Date of first enrolment
01/03/2025

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
Switzerland

Study participating centre
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Sponsor information

Organisation
MOMM Diagnostics GmbH

Funder(s)

Funder type
Industry

Funder Name
MOMM Diagnostics GmbH

Funder Name
Kantonsspital Baden

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date