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Lumella test for detection of pre-eclampsia

Submission date 26/10/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/11/2023	**Overall study status** Completed	
Last Edited 03/02/2025	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Preeclampsia is a condition affecting 5% of pregnancies, characterised by raised blood pressure. It can result in complications affecting the mother with organ failure and is a recognised cause of maternal death. It can also result in early delivery which exposes the baby to short- and long-term complications. Early detection and management improve outcomes and reduce the associated risks.The aim of this study is to examine a new test (Lumella) and compare its performance to a standard test.
Lumella uses a pinprick of blood to provide a bedside result for preeclampsia risk in 10 minutes. It is proposed to replace the current test that requires a blood sample to be sent to the laboratory, meaning a longer wait for results and delaying treatment

Who can participate?
Patients aged 18 years or older with a single or twin pregnancy (gestational age between 24+0 to 36+6 weeks) and a risk of preeclampsia

What does the study involve?
The Lumella test will be performed. A fingerprick blood sample will be collected and tested by the research team and the results will not be shared with either the participant or the clinical team. The treatment and care of participants will be still based on the standard test. The researchers will invite the participants to two further visits in 2 and 4 weeks, if not delivered earlier, and repeat the Lumella test and the standard test. Anonymous data about pregnancy, delivery and neonatal outcomes will be collected to compare the performance of the tests.

What are the possible benefits and risks of participating?
The benefits of participating are a potential earlier diagnosis of pre-eclampsia. There are no additional risks compared to existing procedures and tests conducted during pregnancy. There are an additional two encounters after recruitment to repeat tests, likely to be integrated into regular antenatal visits for planned follow-up.

Where is the study run from?
St George's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2023 to April 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Amarnath Bhide, abhide@sgul.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
329734

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 329734, CPMS 59650

Study information

Scientific Title
Comparison of glycosylated fibronectin test (Lumella®) with sFLT/PLGF ratio test for assessment of pre-eclampsia

Study objectives
In cases with suspected preeclampsia (population), how accurate is the Lumella test (intervention) in detecting a risk of delivery for pre-eclampsia in the next 4 weeks (outcome), in

comparison to sFlt/PlGF ratio (comparator- standard care). Cases with a risk of preeclampsia (possible participants) will be identified based on standard medical history and clinical risk factors in current use in the NHS.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/10/2023, London - Harrow Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)207 1048 154; harrow.rec@hra.nhs.uk), ref: 23/PR/0960

Study design
Observational prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pre-eclampsia

Interventions
The study aims to test the performance of the Lumella test against the sFlt/PlGF ratio (standard test) for the prediction of the risk of preeclampsia. The proposed design is a prospective cohort i.e., participants' notes will be reviewed to detect who will develop preeclampsia and if delivery was required within 4 weeks.

This is a multicentre study that will be conducted in the maternity units of St George’s, Epsom and St Helier NHS hospitals.

Participants in the study will be offered the Lumella test alongside the standard test (sFlt/PlGF ratio) for assessment of preeclampsia risk.

Cases at risk will be identified by the clinical team based on clinical and/or medical history criteria during routine antenatal care visits. The study will be discussed with potential participants by the research team and informed written consent will be obtained.

The Lumella test will be performed by the research team using a fingerstick whole blood sample. Results will be recorded as encrypted code.

Participants and the clinical team will remain blinded to the results. Further management of participants will be based on results from the standard of care test, no change in management will be based on the study.

Participants will be invited to further visits in 2 and 4 weeks if not delivered beforehand. In each visit the Lumella test will be repeated and results recorded, a blood sample will also be collected and sent to a laboratory to test for sFlt/PlGF ratio.

Upon enrolment, a unique Subject Identification number (SID) will be assigned. The SID will be recorded in the Enrolment Log and used throughout the study to identify each participant and preserve participants' confidentiality. Participants' medical records will be reviewed and data about the course of pregnancy, delivery and neonatal outcomes will be collected. Data will be stored in study sites on a secure NHS computer.

Intervention Type
Biological/Vaccine

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lumella Test

Primary outcome measure
Delivery for confirmed preeclampsia within 4 weeks of testing, collected from participants' medical records. The sensitivity for this outcome is compared between Lumella and sFLT/PLGF as non-inferiority.

Secondary outcome measures
1. Preeclampsia diagnosed within 7 and 28 days of sampling, collected from participants' medical records
2. Preeclampsia diagnosed later stage up to postpartum, collected from participants' medical records
Results will be expressed in terms of the sensitivity and specificity of the test

Overall study start date
01/05/2023

Completion date
30/04/2025

Eligibility

Key inclusion criteria

Potential participants include cases with a risk of preeclampsia who meet the following criteria at the time of enrolment:
1. Age of 18 years or older
2. Singleton or twin pregnancy
3. Gestational age between 24+0 to 36+6 weeks
4. Able to provide informed written consent
5. Planned delivery at the study site or where maternal and newborn records will be available to the investigator for review

Cases with a risk of preeclampsia will be identified based on clinical and medical history criteria as follows:

Clinical risk factors:
1. Systolic blood pressure ≥130 mmHg on 1 or more occasion
2. Diastolic blood pressure ≥80 mmHg on 1 or more occasion
3. Elevated urinary protein:
3.1. Urine protein dipstick test 1+ or more
3.2. Urinary protein/creatinine ratio ≥0.30 mg/mg
3.3. Urinary protein ≥300 mg per day in timed collection
4. New onset low platelet count ≤100,000 x 109/L
5. New onset elevated serum creatinine ≥1.0 mg/dL
6. New onset transaminase elevation above limits of normal for local laboratory
7. New-onset headache unresponsive to medication and not accounted for by alternative diagnoses
8. New onset visual symptoms
9. Fetal growth restriction with estimated fetal weight below 10th percentile

Historical/obstetrical risk factors:
1. History of preeclampsia
2. Multifetal pregnancy
3. Pre-existing hypertension
4. Pre-gestational diabetes mellitus
5. Pre-existing renal disease

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
400

Key exclusion criteria

1. Diagnostic criteria for preeclampsia already met at the time of enrolment
2. Delivery is planned prior to 37+0 weeks of gestation for reasons other than preeclampsia

Date of first enrolment
30/11/2023

Date of final enrolment
01/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's Hospital
Blackshaw Rd
London
United Kingdom
SW17 0QT

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
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Study participating centre
Kingston Hospital
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Sponsor type
Industry

Website
https://aghealth.co.uk/

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The potential plan is for publication in a peer-reviewed journal, conference presentation and publication on websites

Intention to publish date

01/02/2026

Individual participant data (IPD) sharing plan

Participants can choose if they wish to be notified of study results at enrolment, as part of the consent form. This will be part of the collected data.
The research team will send out final results via recorded email to those who wish to be notified after publication.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/02/2025	03/02/2025	Yes	No