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Using eye blood vessel scans to help predict high blood pressure and poor baby growth in pregnancy

Submission date
02/07/2025

Recruitment status
Not yet recruiting

Registration date
04/02/2026

Overall study status
Ongoing

Last Edited
09/12/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Preeclampsia (PE) affects 5-8% of pregnancies and can lead to significant maternal and fetal complications. Current diagnostic practices for PE and fetal growth restriction (FGR) primarily rely on blood pressure measurements and maternal and fetal Doppler evaluations. Although maternal Doppler is widely used to predict PE, it does not prevent the condition, with patients at risk only receiving close surveillance. It is, therefore, critical to develop more accurate predictive tests to identify women at high risk of developing PE to prevent complications or the condition itself. Maternal ophthalmic artery Doppler (MOAD) is an advanced, non-invasive, easy-to-perform, and safe tool that shows promise as an adjunctive method for predicting both PE and FGR. This method builds on the success of the middle cerebral artery (MCA) Doppler technique, which predicts FGR due to reduced resistance and increased blood flow to the fetal brain. Increased resistance in the maternal ophthalmic artery has been observed in cases of gestational hypertension and has been validated in preeclamptic pregnancies. Alterations in maternal ophthalmic artery Doppler flow patterns, including increased resistance and reduced diastolic flow, have been linked to an increased risk of FGR. These changes suggest compromised maternal and placental circulation, which adversely affects fetal growth. This pathophysiological framework supports the idea that ocular arteries could serve as valuable markers of hypertension and PE. Additionally, numerous studies have explored the link between retinal artery Doppler and the risk of developing chronic hypertension postpartum. The overall study objective is to evaluate the predictive value of maternal ophthalmic artery Doppler in screening and identifying pregnancies at risk for PE and FGR leading to preterm delivery compared to traditional predictive methods.

Who can participate?
Women with singleton pregnancies who are 20 weeks of gestation and above, attending the antenatal clinic for routine follow-up

What does the study involve?
This study will be a randomly allocated and controlled trial with two parallel groups:
1. Intervention Group: Participants will receive standard prenatal care plus a maternal

ophthalmic artery Doppler measurement.
2. Control Group: Participants will receive standard prenatal care without ophthalmic artery Doppler measurement.

What are the possible benefits and risks of participating?
This study will demonstrate the use of a low-cost modality that is easily available in a clinical setting to screen for PE that is associated with placental insufficiency, leading to FGR. Identifying these high-risk cases will aid in providing antenatal care that aims to reduce maternal and neonatal morbidity, which has a significant impact on the healthcare economy.

This study will be very low risk, as this research is carried out by performing a scan on the mother's ophthalmic artery Doppler flow during antenatal follow-up. There is a low possibility of a risk of allergic reaction to the ultrasound gel and eye irritation while scanning patients.

Where is the study run from?
Department of Obstetrics & Gynaecology, Universiti Malaya Medical Centre, Malaysia

When is the study starting and how long is it expected to run for?
December 2026 to September 2027

Who is funding the study?
Institute of Research Management and Services, University of Malaysia, Malaysia

Who is the main contact?
Dr Rajeev Kumar Rajaratnam, rajeev.kumar@um.edu.my

Contact information

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Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Maternal ophthalmic artery Doppler as an adjunct in prediction of preeclampsia and fetal growth restriction

Study objectives
Maternal ophthalmic artery Doppler analysis is a useful tool as an adjunct to predict preeclampsia and fetal growth restriction.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 24/06/2025, Research Registry and Data Coordination Unit (NMRR Secretariat), National Medical Research Register (Level 2, Blok A1, National Institutes of Health (NIH), No 1 Jalan Setia Murni U13/52, Seksyen U13 Bandar Setia Alam, Shah Alam, 40170, Malaysia; +603-3362 8205/8079/8898; nmrr@moh.gov.my), ref: RSCH ID-25-03729-NO5

Study design
Randomized controlled trial with two parallel groups

Primary study design
Interventional

Study type(s)
Diagnostic, Screening

Health condition(s) or problem(s) studied

Maternal ophthalmic artery Doppler analysis as an adjunct to predict preeclampsia and fetal growth restriction in women with singleton pregnancies who are 20 weeks of gestation and above, attending the antenatal clinic for routine follow-up

Interventions

This study will demonstrate the use of a low-cost modality that is easily available in a clinical setting to screen for preeclampsia that is associated with placental insufficiency, leading to fetal growth restriction. Identifying these high-risk cases will aid in providing antenatal care that aims to reduce maternal and neonatal morbidity, which has a significant impact on the healthcare economy.

Women with singleton pregnancies who are 20 weeks of gestation and above, attending the antenatal clinic for routine follow up in the Department of Obstetrics & Gynaecology of Universiti Malaya Medical Centre will be offered to participate in this study.

Allocation will be performed using a computer-generated randomisation sequence with the use of numbered, opaque and sealed envelopes. Patients will be allocated to receive standard prenatal care or standard prenatal care plus maternal ophthalmic artery Doppler (MOAD) measurement.

This will be a randomized controlled trial with two parallel groups:
1. Intervention Group: Participants will receive standard prenatal care plus a maternal ophthalmic artery Doppler measurement.
2. Control Group: Participants will receive standard prenatal care without ophthalmic artery Doppler measurement.

Patients will attend a baseline antenatal visit where maternal demographic information will be collected via a questionnaire. Maternal height, weight, blood pressure and mean arterial pressure will be measured and recorded using validated instruments. Ultrasound assessment of fetal anatomy and growth, followed by the maternal uterine artery pulsatility index (UtA-PI), is performed. The patient is positioned supine, and a low-frequency curvilinear transducer (2-5 MHz) is used to measure the pulsatility index (PI) and resistance index (RI).

The participants will be assessed on their risk factors for developing preeclampsia based on NICE guidelines and the calculator software by the Fetal Medicine Foundation.

The participants allocated to the MOAD group will then undergo ophthalmic artery Doppler assessment. The participant will be placed in supine position, and a 6–15-MHz linear transducer will be placed transversely and gently over her closed upper eyelid after application of conduction gel. Colour flow will be used to identify the ophthalmic artery, Pulsed-wave Doppler will be used to record three to five similar waveforms; the angle of insonation to be kept at <20, sample gate of 2 mm, depth of 3.0–4.5 cm. Waveforms are to be obtained in sequence from the right eye, left eye, and again from the right and then left eye. The first and second peak systolic velocities will be measured, and the average of 4 measurements will be used for analysis.

Each participant will have a follow-up on a four-week basis up to 36 weeks of gestation or until a diagnosis of preeclampsia or fetal growth restriction is made. Participants allocated to the routine antenatal care arm will be monitored for maternal blood pressure, fetal growth and Doppler studies during each visit. Those allocated to the intervention group will have the

maternal ophthalmic artery Doppler assessed in addition to the other parameters that are of the control group. Should a participant be diagnosed with sudden fetal death or if there is noncompliance with follow-up, the participant will be excluded from the study.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Incidence of preeclampsia, diagnosed based on the new onset of high blood pressure after 20 weeks of gestation associated with maternal proteinuria, neurological dysfunction and/or liver dysfunction, acute kidney injury, hemolysis, thrombocytopenia, and/or fetal growth restriction measured using data collected from patient medical records at one time point

2. Incidence of fetal growth restriction (FGR) measured using the Delphi procedure by measuring abdominal circumference (AC) < 3rd centiles, estimated fetal weight (EFW) < 3rd centiles and absent end-diastolic flow in the umbilical artery (UA) at 20 weeks of gestation until full term

Key secondary outcome(s))
1. Incidence of preterm birth, at which the delivery of the baby occurs in less than 37 weeks of gestation measured using data collected from patient medical records at one time point

2. Neonatal outcomes including Apgar scores, birth weight, and admission to the neonatal intensive care unit (NICU) measured using data collected at the newborn baby assessment at birth

3. Maternal outcome: mode of delivery (vaginal birth or caesarean section) measured using the monitoring of maternal blood pressure and recording of neurological symptoms at time of diagnosis until 42 days postpartum

4. Maternal outcome: timing of delivery (at which delivery in view of the prevalence of preeclampsia as a maternal factor or fetal contributing factor in leading to premature delivery) (<37 weeks of gestation) measured using the monitoring of maternal blood pressure and recording of neurological symptoms at time of diagnosis until 42 days postpartum

5. Maternal outcome: severe maternal complications due to complications of the intrapartum event, such as placental abruption, postpartum hemorrhage measured using the monitoring of maternal blood pressure and recording of neurological symptoms at time of diagnosis until 42 days postpartum

Completion date
01/09/2027

Eligibility

Key inclusion criteria
1. Pregnant women ≥ 20 - 36 weeks of gestation
2. Maternal age of 18-46 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
46 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Pregnant women below 20 and above 36 weeks of gestation
2. Fetal anomalies/Aneuploidy
3. Pre-existing ocular disease
4. Previous ocular surgery
5. On medications that interfere with ocular blood flow
6. Preeclampsia diagnosed in the index pregnancy

Date of first enrolment
15/12/2026

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
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Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Research Management and Services, University of Malaya

Alternative Name(s)
Institute of Research Management & Services, Institute of Research Management and Services, Institute Of Research Management & Monitoring, University Of Malaya, Universiti Malaya Institute of Research Management and Services, The Institute of Research Management & Services at the University Of Malaya, IPPP

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Rajeev Kumar Rajaratnam, rajeev.kumar@um.edu.my, and Dr Wu Pey Ye, email: wupeyye@ummc.edu.my.

• The type of data that will be shared – Participant information sheet
• Timing for availability – based on request
• Whether consent from participants was required and obtained - Yes
• Comments on data anonymization - Yes
• Any ethical or legal restrictions - Yes
• Any additional comments – Nil

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes