ISRCTN10900816 https://doi.org/10.1186/ISRCTN10900816

Improving fetal growth restriction detection

Submission date 06/03/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 15/03/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/06/2025	**Condition category** Neonatal Diseases	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Fetal growth restriction (FGR) refers to babies that are born smaller than the general population. FGR affects 10% of all pregnancies. FGR fetuses are at significantly higher risk of complications, including fetal death and premature birth. FGR deliveries in Malaysia are increasing every year. The current detection technique is not perfect and is reported to miss 50% of FGR before birth. There is thus an urgent need to investigate new technology to improve FGR detection.
Evidence has shown that artificial intelligence (AI) is feasible for disease prediction /prognostication but there is a lack of studies in obstetrics. In this study, the goal is to develop AI technology to improve outcomes with early FGR detection using antenatal measurements and maternal serum biomarkers.

Who can participate?
Pregnant women aged between 18 to 50 years who attend Universiti Malaya Medical Center for pregnancy scanning

What does the study involve?
In Phases 1 and 2, the researchers will extract data from the past 10 years (June 2011 - May 2020). In Phase 3, they will recruit pregnant mothers with a low or high risk of FGR from January to December 2024 and take blood samples.

What are the possible benefits and risks of participating?
There is no expected immediate benefit to the participants. However, the data is expected to generate useful scientific knowledge in the long term. For Phases 1 and 2, no risk will be involved because the researchers are extracting data from a database. In Phase 3, one potential risk is that taking blood may cause discomfort. However, the researchers will only take the blood test after obtaining the patient's consent and any patients who are deemed not fit to take blood tests by the physicians will not be recruited.

Where is the study run from?
Universiti Malaya Medical Center (Malaysia)

When is the study starting and how long is it expected to run for?
May 2021 to June 2025

Who is funding the study?
Ministry of Science, Technology and Innovation (Malaysia)

Who is the main contact?
1. Dr Rahmah bin Saaid, rahmah@ummc.edu.my
2. Dr Saw Shier Nee, sawsn@um.edu.my

Contact information

Type(s)
Principal investigator

Contact name
Dr Shier Nee Saw

Contact details
Faculty of Computer Science and Information Technology
Kuala Lumpur
Malaysia
59200
+60 (0)3 79676341
sawsn@um.edu.my

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
An AI-driven fetal monitoring model to predict fetal growth restriction infants

Study objectives
1. To enable early identification of fetuses at risk for fetal growth restriction (FGR) via the development and design of a personalized AI-based risk prognostic algorithm based on retrospective data of delivered infants
2. To enhance clinical fetal surveillance and management by differentiating between a true FGR and constitutional small for gestational age (SGA) and hence reduce morbidity risks
3. To evaluate the AI risk prognostic algorithm sensitivity of FGR detection with information from the developed AI using prospective new data and maternal serum biomarkers

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 26/08/2021, Medical Research Ethics Committee, University Malaya Medical Centre (2nd floor, Kompleks Pendidikan Sains Kejururawatan, Pusat Perubatan Universiti Malaya 59100 Kuala Lumpur, Malaysia; +60 (0)3 7949 3209 / 2251 / 8473 / 4656; ummc-mrec@ummc.edu.my), ref: 2021329-9997

Study design
Single-center observational longitudinal study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Fetal growth restriction, small-for-gestational-age

Interventions
In this research, the participants will undergo routine prenatal ultrasound scans throughout the entire pregnancy. This involves approximately five scans in total, which are conducted during the first, second and third trimesters. Besides that, the participants will have a non-invasive blood test during the first ultrasound scan, where 5 ml of blood will collect one time only. Every scan measures the fetus's growth to identify the growth-restricted fetuses earlier and take action to improve the outcomes for the growth-restricted fetus. The total duration of observation is typically from Week 11-14 until Week 36, which is around 6 months. The frequency of scans varies depending on the fetus’s condition, with some participants requiring weekly or bi-weekly scans.

Intervention Type
Other

Primary outcome(s)
Maternal information and fetal measurements recorded using ultrasound at first (around 11-14 weeks), second (around 20-22 weeks) and third trimester (around 30-32 weeks)

Key secondary outcome(s))
1. Maternal demographics recorded from patient files at the first visits
2. Fetal measurements measured using ultrasound over the pregnancy period (11-14 weeks, 20-22 weeks, 30-32 weeks, and 35-36 weeks)
3. Maternal serum biomarkers measured using blood tests during the first trimester

Completion date
30/06/2025

Eligibility

Key inclusion criteria

Inclusion criteria for Phases 1, 2 and 3:
1. Pregnant women with age of between 21 and 50 years
2. Subjects are already scheduled for routine antenatal ultrasound evaluation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Upper age limit
50 years

Sex
Female

Total final enrolment
300

Key exclusion criteria
Phases 1 and 2:
1. Fetuses with chromosomal and cardiovascular abnormalities and cases with incomplete data

Phase 3:
1. Patients who, for any reason, are deemed unfit for blood taking, as determined by their physician
2. Fetus with chromosomal and cardiovascular abnormalities

Date of first enrolment
01/02/2023

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
Jalan Profesor Diraja Ungku Aziz, Lembah Pantai
Kuala Lumpur

Malaysia
59100

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
Government

Funder Name
Kementerian Sains, Teknologi dan Inovasi

Alternative Name(s)
Ministry of Science, Technology and Innovation, Malaysia, MOSTI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rahmah bin Saaid (rahmah@ummc.edu.my) and Dr Saw Shier Nee (sawsn@um.edu.my) subject to approval from the ethics committee.

IPD sharing plan summary
Available on request