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Planned early delivery for pregnant women with late preterm pre-eclampsia using placental growth factor testing, compared with usual care, in low- and middle-income countries

Submission date
05/02/2026

Recruitment status
Recruiting

Registration date
18/02/2026

Overall study status
Ongoing

Last Edited
13/02/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

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Study information

Scientific Title
Placental growth factor testing and planned early delivery for late preterm pre-eclampsia, compared to usual care
in low- and middle-income countries (PAPAGAIO-Delivery): an individualised randomised controlled trial

Acronym
PAPAGAIO-Delivery

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/01/2026, King's College London (3rd Floor, 5-11 Lavington Street, London, SE1 0NZ, United Kingdom; +44 020 7848 8888; rec@kcl.ac.uk), ref: HR-25/26-46663

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic, Prevention

Study type(s)

Health condition(s) or problem(s) studied
Pregnancy complicated by late preterm pre-eclampsia

Interventions
This is an international, multi-centre, parallel-group, individually randomised controlled trial conducted in hospitals in Sierra Leone, Zambia, India, and Brazil. Pregnant women presenting with hypertension between 34+0 and 36+6 weeks of gestation will be screened for eligibility.

Interventions Group
The intervention is Placental growth factor (PlGF) testing, plus planned early delivery for women with an abnormal PlGF concentration (less than 100 pg/ml) or expectant management for women with a normal PlGF concentration (above 100 pg/ml). Planned delivery to be undertaken as soon as it is safe and feasible. The target will be to commence delivery within 48 hours from randomisation. The use of antenatal corticosteroids for fetal lung maturity will be at the discretion of the clinician in accordance with local guidelines. Delivery will be through induction of labour according to the local protocol (typically administration of misoprostol) or via caesarean section for women in whom an elective procedure was planned; caesarean section will be an option where indicated.

Interventions – Control Group
Participants allocated to the control group will receive usual care in accordance with local and international clinical guidelines for the management of late preterm pre-eclampsia (34+0 to 36+6 weeks' gestation). This includes routine maternal and fetal monitoring, antihypertensive and anticonvulsant treatment where indicated, and timing of delivery based on standard clinical assessment and existing practice. Delivery is typically recommended at 37 weeks' gestation unless earlier delivery is clinically indicated due to maternal or fetal deterioration. PlGF testing will not be used to guide management decisions in the usual care group.

Randomisation Method
Randomisation will be conducted using a secure web-based randomisation system hosted by OMDA (previously MedSciNet), which will manage allocation and hold the allocation code.

Intervention Type
Device

Phase

Phase III

Drug/device/biological/vaccine name(s)
Placental growth factor testing

Primary outcome(s)
1. Maternal severe adverse outcome composite, defined with standardised clinical criteria including severe pre-eclampsia complications and severe hypertension >160 mmHg, from randomisation until primary hospital discharge of the mother, measured using data collected from clinical and hospital record documentation at one time point

2. Perinatal death from birth until primary hospital discharge of the baby measured using data collected from clinical and hospital record documentation of stillbirth or early neonatal death within seven days of life at one time point

Key secondary outcome(s))

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Hypertension
2. 34+0-36+6
3. Singleton pregnancy
4. Viable fetus at the time of randomisation
5. Able to give informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 years

Upper age limit
60 years

Sex
Female

Total final enrolment
0

Key exclusion criteria

1. In labour
2. Decision to deliver within 48 hours already made (including due to indication for immediate delivery, as defined by WHO guidelines and standard local practice)

Date of first enrolment
23/02/2026

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
Brazil

India

Sierra Leone

Zambia

Study participating centre
University Teaching Hospital
Zambia

Study participating centre
Kabwe Central Hospital
India

Study participating centre
Kitwe Teaching Hospital
Zambia

Study participating centre
Ndola Teaching Hospital
Zambia

Study participating centre
Botucatu Medical School, Sao Paulo State University
Brazil

Study participating centre
Campinas State University
Brazil

Study participating centre
Sao Paulo State University
Brazil

Study participating centre
Federal University of Minas Gerais
Brazil

Study participating centre
Brasilia University
Brazil

Study participating centre
Federal University of Penanbuco
Brazil

Study participating centre
Princess Christian Maternity Hospital, Freetown
Sierra Leone

Study participating centre
Aberdeen Women's Centre
Sierra Leone

Study participating centre
KIMS Hubli
India

Study participating centre
BLDE Sri B M Patil Medical College, Vijayapura
India

Study participating centre
PGIMER, Bhubaneswar
India

Study participating centre
SMS Medical College, Jaipur
India

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	version 3	30/01/2026	12/02/2026	No	No
Participant information sheet	version 4	28/01/2026	06/02/2026	No	Yes
Participant information sheet	version 3	30/01/2026	06/02/2026	No	Yes
Protocol file	version 2	30/01/2026	06/02/2026	No	No