

# 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

<b>Submission date</b> 05/02/2026	<b>Recruitment status</b> Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2026	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/02/2026	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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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## **Additional identifiers**

**National Institute for Health and Care Research (NIHR)**

156828

## **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?
<a href="#">Other files</a>	version 3	30/01/2026	12/02/2026	No	No
<a href="#">Participant information sheet</a>	version 4	28/01/2026	06/02/2026	No	Yes
<a href="#">Participant information sheet</a>	version 3	30/01/2026	06/02/2026	No	Yes
<a href="#">Protocol file</a>	version 2	30/01/2026	06/02/2026	No	No