ISRCTN13961105 https://doi.org/10.1186/ISRCTN13961105

The CAMELIA study: How mothers' health and environment affect their baby's start in life in Cameroon

Submission date
28/07/2025

Recruitment status
Recruiting

Registration date
14/08/2025

Overall study status
Ongoing

Last Edited
15/12/2025

Condition category
Pregnancy and Childbirth

[_] 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
A mother's health and environment during pregnancy can have a major impact on her baby's health at birth and beyond. In Cameroon, many pregnant women are exposed to risk factors such as poor nutrition, gestational diabetes, and environmental substances like alcohol or pesticides. This study aims to understand how these factors affect maternal and newborn health. It also evaluates whether sending health messages by phone (SMS or WhatsApp) can help pregnant women adopt healthier behaviours during pregnancy.

Who can participate?
Women can take part in the study if they:
1. Are aged 15 years or older (with parental or guardian consent if under 18 years)
2. Are less than 22 weeks pregnant at their first antenatal care visit
3. Are expecting one baby (not twins or triplets)
4. Live in Yaoundé IV or Yaoundé VI
6. Receive care at the CASS Nkolndongo maternity facility
7. Agree to give written consent to participate

What does the study involve?
All participants receive standard prenatal care along with a nutritional education programme through group talks and one-on-one counselling. Some participants also receive follow-up messages via WhatsApp or SMS to reinforce key messages about healthy eating, avoiding alcohol, taking supplements, and staying active. A subgroup may wear a smartband to help monitor physical activity.
All participants attend four study visits: early pregnancy, mid-pregnancy, at delivery, and 6 weeks after childbirth. At each visit, they answer questionnaires, have health checks, and provide small samples of blood or urine. At birth, samples of the baby's cord blood and placenta are also collected for research.

What are the possible benefits and risks of participating?
Benefits: Participants receive additional health education and screening, including for

gestational diabetes. Women receiving mobile messages may find them helpful in maintaining healthy habits.
Risks: The main risk is minor discomfort from blood sampling. Participants also spend some time attending study visits and answering questions.

Where is the study run from?
The study is being run in Yaoundé, Cameroon. Participants will be recruited from two healthcare centres: CASS Nkolndongo and the Biyem-Assi District Hospital.

When is the study starting and how long is it expected to run for?
May 2025 to September 2028

Who is funding the study?
The study is funded by the RSD Institute (Health Research and Intervention), a research organization based in Cameroon.

Who is the main contact?
Prof. Eugene Sobngwi, eugenesobngwi@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
WDF22-1902

Study information

Scientific Title
The Cameroon Maternal & Early Life Study (CAMELIA) – a prospective study investigating maternal health, environmental exposures, and perinatal outcomes in Cameroon

Acronym
CAMELIA

Study objectives
1. To determine the environmental and maternal predictors of pregnancy outcomes in a prospective cohort of women in Cameroon.
2. To assess the effectiveness of a nutritional education programme on reducing gestational diabetes incidence.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/05/2025, National Ethical Committee for Research on Human Health (-, Yaoundé, 1937, Cameroon; +237 (0)243 67 43 39; cnersh@yahoo.com), ref: 2025/04/1790/CE/CNERSH/SP

Study design
Prospective open-label controlled quasi-experimental study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Maternal and perinatal health in pregnant women in Cameroon, including pregnancy outcomes and neonatal health. The study focuses on gestational diabetes, nutritional status, and environmental exposures (e.g. alcohol, pesticides) and their potential impact on fetal development and early-life outcomes.

Interventions
Participants are assigned to a study arm non-randomly based on the healthcare facility they attend for their prenatal care. The target allocation ratio is 4:1 (intervention to control).

Intervention arm (recruited from CASS Nkolndongo):
Participants in this arm receive Standard Prenatal Care plus a comprehensive Nutritional Education Programme. The intervention consists of:
1. Educational Sessions: Structured group talks and individual counseling on topics including essential food groups, the importance of a diversified diet, physical activity, foods to avoid (e.g., alcohol), and adherence to iron and folic acid supplementation.
2. Digital Sensitization: Ongoing engagement and health messaging delivered via WhatsApp and SMS to reinforce learning and encourage good practices.
3. Activity Monitoring: A sub-sample of participants will be provided with a connected smartband to monitor health parameters such as physical activity.

Control arm (recruited from the District Hospital of Biyem-Assi):
Participants in this arm receive Standard Prenatal Care. The nutritional education programme is intentionally delayed for this group and will be provided at a later stage.

Common procedures for all participants (both arms):
Regardless of their assigned arm, all participants undergo a standardized follow-up which includes screening for gestational diabetes, measurement of exposure to alcohol and pesticides, collection of biological samples (maternal blood/urine, cord blood) for a biobank, anthropometric measurements, and questionnaire completion at key study visits throughout their pregnancy (Visit 1 at the enrolment, Visit 2 between 24th and 32th weeks of gestation, and V3 during delivery) and at 42 days postpartum.

Intervention Type
Behavioural

Primary outcome(s)
Incidence of Gestational Diabetes Mellitus (GDM)
Measurement: GDM will be diagnosed using a multi-step screening and diagnostic protocol, including fasting capillary glucose testing and, if indicated, a 75 g oral glucose tolerance test (OGTT). Diagnosis follows WHO criteria.
Outcome: The primary outcome is the proportion of women diagnosed with GDM, compared between those who receive digital reinforcement via WhatsApp/SMS and those who receive only in-person education.
Timepoint: Screening is conducted primarily at Visit 2 (24–32 weeks of gestation), with additional assessments at Visit 1 (<22 weeks) and postpartum at Visit 4 (42 days after delivery).

Key secondary outcome(s))
Maternal outcomes:
1. Gestational weight gain, measured using a digital scale at each visit, from Visit 1 (<22 weeks) to Visit 3 (delivery).
2. Change in blood pressure, measured using a digital sphygmomanometer at each visit; comparison of mean systolic and diastolic values between Visit 1 and subsequent visits.
3. Changes in body composition (BMI, body fat percentage, visceral fat), assessed using bioelectrical impedance analysis at Visit 1, Visit 2 (24–32 weeks), and Visit 4 (42 days postpartum).

Perinatal and neonatal outcomes:
4. Birth weight, measured using a calibrated infant scale at delivery (Visit 3).
5. Incidence of low birth weight (<2500 g), assessed at delivery (Visit 3).
6. Incidence of macrosomia (>4000 g), assessed at delivery (Visit 3).
7. Apgar score at 1 and 5 minutes after birth, recorded by clinical staff at delivery (Visit 3).
8. Incidence of preterm birth (<37 completed weeks of gestation), assessed at delivery (Visit 3).

Behavioural and exposure-related outcomes:
9. Change in nutritional knowledge and practices, assessed using a structured questionnaire at Visit 1 and Visit 2.
10. Level of exposure to pesticides and alcohol, measured using biomarkers in maternal blood, urine, hair, and nail samples collected at Visit 1, Visit 2, and Visit 3.
11. Change in physical activity, assessed through step counts from a smartband worn by a sub-

sample of participants throughout the study period.
12. Epigenetic modifications, assessed in postnatal biological samples (cord blood and placenta) collected at delivery (Visit 3); analysis planned in future secondary investigations.

Completion date
12/09/2028

Eligibility

Key inclusion criteria
Participants must meet all of the following criteria:
1. Aged 15 years or older at the time of enrolment.
2. Presenting for their first antenatal care visit before 22 weeks of gestation.
3. Confirmed singleton pregnancy.
4. Resident of Yaoundé IV or Yaoundé VI, Cameroon.
5. Able and willing to provide written informed consent.
6. If aged under 18 years, parental or legal guardian consent is also required in accordance with national ethical guidelines.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 years

Upper age limit
49 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Participants will be excluded if they meet any of the following:
1. Known diagnosis of a severe pre-existing chronic condition, such as:
1.1. Pre-existing diabetes mellitus
1.2. Severe renal insufficiency
1.3. Sickle cell disease
1.4. Cancer
2. Multiple pregnancy (e.g. twins, triplets).
3. Threatened miscarriage or imminent preterm labour diagnosed at the time of enrolment.

Date of first enrolment
12/05/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Cameroon

Study participating centre
Hôpital MonSeigneur Jean Zoa
PO Box 185
Yaoundé
Cameroon
185

Study participating centre
District Hospital of Biyem Assi
PO Box 11984
Yaoundé
Cameroon
11984

Sponsor information

Organisation
RSD Institute

Funder(s)

Funder type
Research organisation

Funder Name
RSD Institute (Health, Research and Intervention)

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 Pr Eugene Sobngwi (eugenesobngwi@gmail.com).

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes