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Ergothioneine and pre-eclampsia study

Submission date 15/09/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/10/2025	**Overall study status** Ongoing	
Last Edited 14/10/2025	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Pre-eclampsia is a condition that can occur during pregnancy, causing high blood pressure and other complications that may affect both the mother and baby. Diet is thought to play an important role in the development and prevention of pre-eclampsia. This study aims to explore whether there are differences in diet quality and in the intake of a naturally occurring nutrient called ergothioneine, found in foods such as mushrooms, between pregnant women who have pre-eclampsia and those who do not. The study will also assess how easy and acceptable two online dietary assessment tools are for pregnant women to use.

Who can participate?
Pregnant women aged 18 years or older diagnosed with and without pre-eclampsia who live in the Liverpool region.

What does the study involve?
Participants will complete a short online survey that first collects essential demographic and clinical information (ethnicity, age, educational levels, occupation, dietary preferences, pre-eclampsia diagnosis and week of pregnancy) and then asks about the frequency of typical food consumption in the last month and specifics about dietary intake in the previous 24 hours. Participants will also be asked to provide feedback on how easy these tools are to use. All data will be collected online and will take around 20-25 minutes to complete in total.

What are the possible benefits and risks of participating?
There are no direct health benefits for participants, but the findings may help researchers better understand how diet relates to pre-eclampsia and improve future dietary advice for pregnant women.
To thank participants for their time, they will receive a £10 voucher once they have completed the study. In addition, a leaflet with information about healthy eating during pregnancy will be sent via email.
There are no known risks to taking part. All data will be collected anonymously and kept strictly confidential. Participants can withdraw from the study at any time without giving a reason.

Where is the study run from?
The study is run by the University of Liverpool, in collaboration with Liverpool Women's Hospital, UK.

When is the study starting and how long is it expected to run for?
January 2025 to March 2027.

Who is funding the study?
The University of Liverpool, UK.

Who is the main contact?
Prof J Bernadette Moore, Biochemistry, Cell and Systems Biology, Institute of Systems, Molecular and Integrative Biology, University of Liverpool, J.Bernadette.Moore@liverpool.ac.uk

Contact information

Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
356273

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UoL001943

Study information

Scientific Title
Investigating dietary ergothioneine and dietary quality in pregnant women with and without pre-eclampsia

Acronym
Erg-PE

Study objectives
1. To survey ergothioneine intake in pregnant women.
2. To compare ergothioneine intakes between those with and without pre-eclampsia.
3. To compare diet quality scores between those with and without pre-eclampsia.
4. To compare dietary nutrient intakes between those with and without pre-eclampsia.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 28/05/2025, HRA and Health and Care Research Wales (HCRW) (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; bloomsbury.rec@hra.nhs.uk), ref: 25/PR/0434

2. approved 18/08/2025, HRA and Health and Care Research Wales (HCRW) (Health Research Authority, 2 Redman Place, Stratford, London, E20 1 JQ, United Kingdom; +44 (0)207 104 8000; bloomsbury.rec@hra.nhs.uk), ref: 25/PR/0434/AM01

Study design
Observational case-control study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Pre-eclampsia

Interventions
Participants will enrol via the secure online REDCap platform. After consenting, they will access a structured online form with seven essential demographic and clinical questions and then a 45-item food frequency questionnaire that evaluates dietary intakes over the past month. Finally, they will then complete a 24-hour dietary recall using the MyFood24 Online Dietary Assessment Tool. This combination of online surveys will take approximately 20-25 minutes on the part of the participant. The duration of follow-up is until pregnancy outcome, which will be ascertained from clinical data.

Intervention Type
Other

Primary outcome(s)
1. Ergothioneine intakes will be measured using a short, validated food frequency questionnaire, which asks participants how frequently (portions per day or week) they consumed typical foods in the last month. Ergothioneine intake will be estimated from reported consumption frequencies of ergothioneine-rich foods (e.g., mushrooms, fermented foods) using nutrient composition data.
2. Dietary quality will be measured using a short, validated Food Frequency Questionnaire (FFQ), which asks participants how frequently (portions per day or week) they consumed typical foods in the last month. Dietary quality is derived from the FFQ responses using a standardised 0–5 scoring system, where optimal intakes receive the highest score.

Key secondary outcome(s))
1. Dietary nutrient intakes will be measured using a 24-hour dietary recall using the MyFood24 Online Dietary Assessment Tool to capture participants' most recent nutrient intakes daily
2. Participant feedback on the usability and acceptability of the Food Frequency Questionnaire (FFQ) will be measured at the point of survey using a self-administered feedback questionnaire that combines Likert-scale and open-ended questions

Completion date
31/03/2027

Eligibility

Key inclusion criteria
Cases:
1. Currently pregnant women, with pre-eclampsia diagnosed according to NICE guidelines (the NICE diagnostic criteria are hypertension [>140/>90 mmHg] and proteinuria/renal insufficiency /liver involvement/neurological complications/haematological complications/uteroplacental dysfunction) attending Liverpool Women's Hospital
2. Able to consent to the study in English

Controls:
1. Currently pregnant, gestationally matched women without pre-eclampsia attending Liverpool Women’s Hospital
2. Able to consent to the study in English

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Cases
1. Not a patient of Liverpool Women’s Hospital
2. Unable to consent in English

Controls
1. Not a patient of Liverpool Women’s Hospital
2. Unable to consent in English
3. Past medical history making them at high risk of pre-eclampsia including chronic hypertension, gestational hypertension, chronic kidney disease, autoimmune diseases
4. Previous pregnancy history making them at high risk of pre-eclampsia including fetal growth restriction, small for gestational age fetus, hypertension in pregnancy, previous pre-eclampsia
5. Current pregnancy risk factors for pre-eclampsia: PAPP-A less than 5th Centile, echogenic bowel, estimated fetal weight less than 10th centile

Date of first enrolment
20/09/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool Women's Hospital
Liverpool Womens Hospital

Crown Street
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
University/education

Funder Name
University of Liverpool

Alternative Name(s)
The University of Liverpool, , Universidad de Liverpool, UoL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The consent forms will be sorted in the study site file in the University of Liverpool Women and Children's Health Research Department located at Liverpool Women's Hospital. This will be retained in the department for 10 years. The case report forms will be identified only by the participant number and entered into the study database and stored separately until the end of the study. After this time, the de-identified, case report forms (CRFs) will be electronically scanned and uploaded into the access controlled ActiveDataStore for archiving.

All electronic research data (uploaded CRFs and results of analysis) will be stored within University of Liverpool data storage infrastructure and will comply with the research data management policy researchdatamanagementpolicy.pdf (liverpool.ac.uk). All data will be password protected and accessible by the necessary members of the research team only. Data which will be used for subsequent analysis will undergo full anonymisation by decoupling of the identifiers from the data. On completion of the study, all study data including consent forms and other participant identifiable information will be stored for a minimum of 10 years.

IPD sharing plan summary

Stored in non-publicly available repository

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