

Toxic metals from diet in pregnancy: the PEAR Study (pregnancy, the environment and nutrition)

Submission date 27/02/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/10/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diet is an important factor for every pregnancy for the health and development of the baby. The NHS in England provides guidance on avoiding or limiting fish and game meat/gamebirds to keep intakes of the toxic metals to a minimum. We don't know how closely women follow this advice and how well following the advice protects women from toxic metals. This information is essential to make sure that the guidance is effective.

We would like to find out how much of these foods women eat during pregnancy and how that affects the amount of the metals in their bodies. We'd also like to find out what they know about the guidance and how that affects their food choices.

We're also interested in arsenic, which can be contained in rice, and whether there should be guidance on this.

Who can participate?

We'll include about 300 women in early pregnancy who live in north Bristol and are booked for delivery at Southmead Hospital.

What does the study involve?

Women will be sent two electronic questionnaires at about 12 weeks of pregnancy to fill in at home. The first will ask them to record everything they eat or drink over 2 days. The second will ask more about how often they eat particular foods, together with some questions about themselves and what they know about the NHS guidance (this second one will be repeated at 32 weeks). At the 12-week hospital scan clinic visit, we'll ask the clinic staff to take some extra blood (less than a teaspoon) into a tube we'll provide to women to be returned in the post. This will be analysed for mercury and lead. At the same time we'll send the women a small plastic bottle in the post to fill with a urine sample at home for return in the post for lead and arsenic measurement.

What are the possible benefits and risks of participating?

The study will not be of any direct benefit to the participants but it will provide information on the diet in pregnancy and the effect on exposures to mercury, lead and arsenic from diet. This will help to guide advice about diet in pregnancy given to women in England.

Where is the study run from?

University of Bristol (UK)

When is the study starting and how long is it expected to run for?

February 2020 to January 2025

Who is funding the study?

Medical Research Council (UK)

Who is the main contact?

Dr Caroline Taylor, caroline.m.taylor@bristol.ac.uk

Contact information

Type(s)

Principal investigator

Contact name

Dr Caroline Taylor

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

321048

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 321048, CPMS 54521

Study information

Scientific Title

Dietary exposures to toxic metals in pregnancy: the PEAR Study (Pregnancy, the Environment And nutRition)

Acronym

PEAR Study

Study objectives

Our main aim is to find out whether women follow the NHS guidance on fish and game meat /gamebirds and whether this has an effect on the quantities of the toxic metals in their bodies.

This aim can be divided as follows.

Dietary intakes

1. How much fish (total, white/oily, shark/marlin/swordfish, tinned tuna, fresh tuna), game meat /gamebirds (e.g. venison, grouse) and rice/rice products (e.g. rice milk, rice cakes) do women eat at 12 and 32 weeks pregnancy?
2. How do these intakes compare with NHS guidance?
3. Is the guidance followed equally well later in pregnancy (32 weeks) compared with early on (12 weeks)?

Toxic metal biomarkers

1. What are blood concentrations of mercury and lead, and urine arsenic concentrations, at 12 weeks?
2. Are these biomarker concentrations linked with dietary intakes of particular foods or combinations of foods?
3. What is the contribution of diet to these concentrations?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/12/2022, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 207 104 8121; southyorks.rec@hra.nhs.uk), ref: 22/YH/0265

Study design

Single centre longitudinal observational cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Exposure to toxic metals in pregnancy

Interventions

Observational study: during pregnancy measurement of biomarkers for lead, mercury and arsenic in blood and urine samples, collection of dietary data, lifestyle and environment questionnaires

Intervention Type

Other

Primary outcome(s)

Biomarkers for lead, mercury and arsenic will be measured in whole blood and urine samples at 12 weeks.

Key secondary outcome(s)

1. Lifestyle and environment information will be collected using an online questionnaire at 12 and 32 weeks.
2. Dietary data will be collected at 12 weeks using an online data collection tool (myfood24).

Completion date

31/01/2025

Eligibility**Key inclusion criteria**

1. Age 18 years and over
2. Pregnant <14 weeks
3. Has internet access
4. Able to read and write English
5. Planning to have blood sample taken at 12-week screening clinic
6. Registered for care at Southmead Hospital, Bristol, UK

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Total final enrolment

313

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/2023

Date of final enrolment

17/05/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Southmead Hospital**

Southmead Road

Westbury-on-trym

Bristol

United Kingdom

BS10 5NB

Study participating centre**University of Bristol**

Centre for Academic Child Health

Bristol Medical School

Canynges Hall

39 Whatley Road

Bristol

United Kingdom

BS8 2PS

Sponsor information

Organisation

University of Bristol

ROR

<https://ror.org/0524sp257>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Anonymised data will be deposited in the University of Bristol Research Data Repository in a form suitable for long-term retention. The Data Repository is managed by the University of Bristol Research Data Service (<http://www.bristol.ac.uk/staff/researchers/data/>). The research data will be deposited at the end of the study.

The data will be reserved for exclusive use until the end of the study, when they will be placed in the repository and available to others under controlled access.

Datasets published via data.bris will appear on the repository catalogue (<https://data.bris.ac.uk/data/>), on the University's research information database, Explore Bristol Research (<https://research-information.bristol.ac.uk/>), and on the DataCite registry (<https://search.datacite.org/>), which are all additionally visible to search engines such as Google. On publication in data.bris, the deposit will be assigned a unique DOI. Published research outputs will include the DOI and a statement on how to apply for access to the dataset.

The outputs will be made available on application to the repository through a facilitated approval process for approved external researchers, who will sign a data-sharing agreement.

Requests for data are assessed by the University's Data Access Committee (<http://www.bristol.ac.uk/staff/researchers/data/accessing-research-data/>).

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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HRA research summary			28/06/2023	No	No
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