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

Submission date
27/02/2023

Recruitment status
No longer recruiting

Registration date
27/02/2023

Overall study status
Completed

Last Edited
30/10/2024

Condition category
Pregnancy and Childbirth

[X] 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
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

Study website
http://pearstudy.com/

Contact information

Type(s)
Principal Investigator

Contact name
Dr Caroline Taylor

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
321048

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 this 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 or 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

Secondary study design
Longitudinal study

Study setting(s)
Home, Hospital, Internet/virtual

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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

Secondary outcome measures
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).

Overall study start date
01/02/2020

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

Age group

Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
300

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
England

United Kingdom

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
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol

Sponsor details
Research and Enterprise Division
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Sponsor type
University/education

Website
https://www.bristol.ac.uk/

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

Publication and dissemination plan
Planned publication in high-impact peer-reviewed academic journals.

Intention to publish date
01/01/2026

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?
HRA research summary			28/06/2023	No	No