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Prenatal iodine nutrition and child attention deficit-hyperactivity disorder

Submission date
12/09/2017

Recruitment status
No longer recruiting

Registration date
14/09/2017

Overall study status
Completed

Last Edited
24/08/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
A lack of certain nutrients (deficiency) during critical phases in brain development may result in irreversible functional changes to the brain, the most critical period being pregnancy (gestation) and the early years of life. There is evidence for a link between low iodine levels during pregnancy and later attention-deficit/hyperactivity disorder (ADHD) in the child, but more studies are needed. Studies are also needed to explore whether iodine supplements in pregnancy can compensate for a lack of iodine in the diet. The WHO currently recommends the use of iodine supplements in pregnancy in areas where pregnant women are at risk of mild- to moderate iodine deficiency, but the recommendation lacks scientific support. Some studies even indicate that starting iodine supplementation in pregnancy might have negative effects. It is very important to clarify these relationships as soon as possible in order to design preventive strategies. The main aim of this study is to examine the possible link between iodine intake from food in pregnancy and the risk of ADHD in the child at age 8 years. A second aim is to explore the links between use of iodine-containing supplements before and during pregnancy and the risk of ADHD.

Who can participate?
Pregnant women in their first trimester recruited from all over Norway during the years 1999 to 2008

What does the study involve?
Participants' iodine intake from food and use of iodine-containing supplements are assessed using questionnaires. ADHD symptoms of the children at age 8 years are assessed by questionnaire, and ADHD diagnoses are obtained from the Norwegian Patient Registry.

What are the possible benefits and risks of participating?
As this is an observational study there are no benefits or risks for the individual participants, but there is a potential large benefit for society and for future generations. The results from this study are communicated to participants through the study website and by newsletters to all participating families.

Where is the study run from?
Norwegian Institute of Public Health (Norway)

When is the study starting and how long is it expected to run for?
August 2016 to December 2017

Who is funding the study?
1. Norwegian Ministry of Health (Norway)
2. Norwegian Ministry of Education and Research (Norway)
3. National Institute of Environmental Health Sciences (USA)
4. National Institute of Neurological Disorders and Stroke (USA)

Who is the main contact?
Dr Anne-Lise Brantsaeter

Study website
https://www.fhi.no/en/studies/moba/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PDB1380

Study information

Scientific Title
Maternal iodine intake and offspring attention deficit-hyperactivity disorder

Study objectives
The main aim of the current study was to explore the association between iodine intake from food in pregnancy (as a proxy for long-term iodine intake and status) and i) risk of specialist-diagnosed ADHD in the child and ii) maternal report of child ADHD symptoms at age 8 years. A second aim was to explore the associations between maternal use of iodine-containing supplements prior to and during pregnancy and the same outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Committee for Medical Research Ethics South East Norway, 20/10/2016, ref: REK 2013/594

Study design
Observational population-based prospective pregnancy cohort

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Community

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
Child ADHD diagnosis and maternally reported child ADHD symptoms at age 8 years

Interventions
1. Maternal iodine intake from food in non-users of supplemental iodine assessed by a food frequency questionnaire in gestational week 22
2. Maternal use of iodine-containing supplements (dosage and time of initiation) assessed by questionnaires in pregnancy (gestational week 17 and 22)

Intervention Type
Other

Primary outcome measure

1. Registered child ADHD diagnosis in the Norwegian Patient Registry (NPR) by Dec. 2015. From 2008, all government-owned and government-financed hospitals and outpatient clinics mandatorily report individual level diagnoses defined in the tenth revision of the International Classification of Disease (ICD-10) to the NPR in order to receive financial reimbursement. Using individual personal identification numbers, diagnostic information from NPR was linked to MoBa. Thus all MoBa children registered with an ICD-10-diagnosis of hyperkinetic disorder (HKD coded as F90.0, F90.1, F90.8, or F90.9) between 2008 and 2015 were identified and regarded as having ADHD
2. Child ADHD symptoms assessed in the 8 year questionnaire from MoBa on a 4-point Likert scale (never/rarely, sometimes, often, or very often) covering inattention problems (9 items) and hyperactivity/impulsivity (9 items) from the ADHD Rating Scale

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/08/2016

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Pregnant women in their first trimester recruited from all over Norway during the years 1999 to 2008 and asked to answer questionnaires (in Norwegian) at regular intervals during pregnancy and after birth
2. To be included in the current study mothers had to have responded to a general questionnaire around gestational week (GW) 17, and a food frequency questionnaire (FFQ) around GW 22
3. Only singleton pregnancies
4. Only participants with information on all covariates were included in the analysis because of the large sample size and low rates of missing values
5. Pregnant women at any age were allowed to participate

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
The total cohort includes more than 100,000 mother-child pairs. A total of 77,164 mother-child pairs were included in this study, and for 27,945 there were data on maternally reported ADHD score at child age 8 years

Total final enrolment

77164

Key exclusion criteria
1. Multiple pregnancies
2. Maternal use of thyroid medication in pregnancy
3. Missing information on important covariates
4. Children registered as dead or emigrated by Jan 2016
5. FFQs with more than 3 blank pages
6. Calculated energy intakes <4.5 MJ or >20 MJ

Date of first enrolment
01/03/2002

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Norway

Study participating centre
Norwegian Institute of Public Health
PO Box 222 Skoyen
Oslo
Norway
NO-0213

Sponsor information

Organisation
The Research Council of Norway

Sponsor details
Postboks 564
Lysaker
Oslo
Norway
1327
+47 (0)22037000
post@forskningsradet.no

Sponsor type
Research council

Website
http://www.forskningsradet.no/en/Home_page/1177315753906

ROR
https://ror.org/00epmv149

Organisation
TINE SA

Sponsor details
Postboks 25
Oslo
Norway
0051

Sponsor type
Industry

Funder(s)

Funder type
Government

Funder Name
Helse- og Omsorgsdepartementet

Alternative Name(s)
Ministry of Health and Care Services

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Funder Name
Utdannings- og forskningsdepartementet

Alternative Name(s)
Norwegian Ministry of Education and Research, UFD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Funder Name
National Institute of Environmental Health Sciences (contract no N01-ES-75558)

Alternative Name(s)
The National Institute of Environmental Health Sciences, NIH National Institute of Environmental Health Sciences, Division of Environmental Health Sciences, National Environmental Health Sciences Center, NIEHS, DEHS

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

Funder Name
National Institute of Neurological Disorders and Stroke (grant no.1 UO1 NS 047537-01 and grant no.2 UO1 NS 047537-06A1)

Alternative Name(s)
National Institute of Neurological Disorders & Stroke, NIH/National Institute of Neurological Disorders and Stroke, NIH National Institute of Neurological Disorders and Stroke, Instituto Nacional de Trastornos Neurológicos y Accidentes Cerebrovasculares, The National Institute of Neurological Disorders and Stroke, National Institute of Neurological Disorders and Blindness, National Institute of Neurological and Communicative Disorders and Stroke, NINDS, NINDB, NINCDS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan

Protocol: https://www.fhi.no/globalassets/dokumenterfiler/moba/pdf/moba-protocol-revised-oct-2012.pdf
This study will result in one publication in an international peer-reviewed journal.

Intention to publish date

01/12/2017

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 24/08/2022:
The consent given by the participants does not allow for the storage of data on an individual level in repositories or journals. Researchers who want access to datasets for replication should apply through helsedata.no. Access to data sets requires approval from The Regional Committee for Medical and Health Research Ethics in Norway and an agreement with MoBa.

Previous IPD sharing statement:
No data can be shared because of data protection regulations. Other researchers, nationally and internationally, will have access to the cohort on request. For more information about research and data access from the Norwegian Mother and Child Cohort Study see: https://www.fhi.no/en/op/data-access-from-health-registries-health-studies-and-biobanks/data-from-moba/research-and-data-access/#protocol

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/11/2017		Yes	No
Protocol (other)			23/08/2022	No	No
Results article		10/04/2016	23/08/2022	Yes	No
Participant information sheet			24/08/2022	No	Yes