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The relationship between nutrition, inflammation and depression in pregnancy and following birth

Submission date	Recruitment status	[X] Prospectively registered
22/09/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2008	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/08/2020	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.rgu.ac.uk/fhsc/core/page.cfm?pge=45441

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The relationship between nutrition, increased inflammation and depression in pregnancy and post-partum: assessment of depression scores, inflammatory cytokines and omega-3 fatty acids

Acronym
DIO-3

Study objectives
Psychological stress and depression increase the production of pro-inflammatory cytokines, and reduce the production of anti-inflammatory/immuno-regulatory cytokines. An increased ratio of omega-6 to omega-3 polyunsaturated fatty acids (PUFAs) in the blood causes an increase in the production of pro-inflammatory cytokines and a reduction in the production of anti-inflammatory cytokines. Population studies have found an inverse relationship between depression and per capita fish consumption; and lower blood/plasma omega-3 FA content has been found in subjects with depression.

Pregnancy and post-partum are associated with immune activation and hypersecretion of pro-inflammatory cytokines and elevated C-reactive protein. Studies have reported low blood omega-3 FA levels in pregnancy and post-partum. Psychological stress and depression are prevalent in pregnancy. Psycho-social risk factors known to be associated with depression increase the prevalence of depression in pregnancy. A higher omega-6 to omega-3 ratio may predict an increase in the production of pro-inflammatory cytokines to psychological stress and depression.

The aim of this study is to investigate the relationship between maternal omega-3 and omega-6 PUFA status (evaluated by the food frequency questionnaire [FFQ] and erythrocyte membrane FA), inflammatory cytokines and depression during pregnancy and post-partum in women at high-risk of depression (a history of psycho-social risk factors associated with perinatal depression) and low-risk of depression; and to assess the potential for the development of specific biomarkers to predict the onset and progression of this condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The North of Scotland Research Ethics Committee, 11th June 2008 (REC Ref: 08/S0801/21)

Study design
Observational prospective (longitudinal) cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Maternal stress and depression

Interventions
This is an observational prospective longitudinal (from first trimester of pregnancy to 6 months post-partum) cohort study, where the data concerning the condition are assembled and observed prior to the condition occurring and when the condition occurs. Patients without depression, but identified as high-risk (psycho-social history of exposure) and low-risk of depression (no psycho-social history of exposure) will be followed and observed for depression, increased inflammation and high omega-6 to omega-3 ratio. The following data will be collected:
1. Assessment of risk factors known to be associated with perinatal depression (Antenatal Risk Questionnaire [ANRQ]; Postnatal Risk Questionnaire [PNRQ])
2. Assessment of perinatal psychological stress and depression (Edinburgh Depression Scale /Edinburgh Postnatal Depression Scale [EDS/EPDS]; Hospital and Anxiety Depression Scale [HADS])
3. Assessment of dietary omega-3 and omega-6 FAs (Scottish Collaborative Group Food Frequency Questionnaire [SCGFFQ])
4. Assessment of erythrocyte membrane omega-3 and omega-6 FA content
5. Assessment of serum inflammatory cytokines
6. Assessment of plasma C-reactive protein

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Differences in depression scores, inflammatory cytokines and CRP concentrations and omega-3 FA status between women at high-risk (a history of psycho-social risk factors associated with perinatal depression) and low-risk of depression
2. Correlations between omega-6 to omega-3 FA ratio, inflammatory cytokines and CRP concentrations and depression scores

Time points:
1. Baseline (13 weeks gestation)
2. 24 weeks gestation
3. 34 weeks gestation
4. 36 hours post-delivery
5. 6 weeks post-partum

6. 12 weeks post-partum
7. 24 weeks post-partum

Secondary outcome measures
1. Incidence of depression in women at high-risk of depression (a history of psycho-social risk factors associated with perinatal depression) and low-risk of depression (measured by the ANRQ and PNRQ) (the ANRQ is used only at baseline; the PNRQ is used only at 36 hours post-delivery)
2. Comparison of depression scores measured by the EDP/EPDS and the HADS
3. Comparison of omega-3 and omega-6 FA intakes measured by the SCGFFQ and erythrocyte membrane content

Time points:
1. Baseline (13 weeks gestation)
2. 24 weeks gestation
3. 34 weeks gestation
4. 36 hours post-delivery
5. 6 weeks post-partum
6. 12 weeks post-partum
7. 24 weeks post-partum

Overall study start date
03/11/2008

Completion date
25/06/2010

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Pregnancy and post-partum
2. Age 18 - 45 years
3. Healthy volunteers
4. Patient under Grampian Healthcare

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants

100

Key exclusion criteria
1. Medical conditions (including obstetric complications) or currently taking medication affecting the immune, endocrine (thyroid dysfunction, diabetes), metabolic, hepatic, renal, and gastrointestinal systems; coagulation disorders and anaemia
2. A history of psychiatric disorders other than depression (mania/hypomania, psychosis, active suicidal ideation, schizophrenia, eating disorders not associated with depression, personality disorders, epilepsy)
3. Taking anti-depressant medication or other remedies for depression (St Johns Wort)
4. A history of alcohol or drug abuse, and tobacco use
5. Assisted conception
6. Taking supplementary fish oils or flax seed
8. Spontaneous miscarriage and termination of pregnancy

Date of first enrolment
03/11/2008

Date of final enrolment
25/06/2010

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
The Centre for Obesity Research and Epidemiology
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Sponsor information

Organisation
The Centre for Obesity Research and Epidemiology (CORE) (UK)

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Sponsor type
Research organisation

Website
http://www.rgu.ac.uk/acero/CORE/

ROR
https://ror.org/04f0qj703

Funder(s)

Funder type
Research organisation

Funder Name
The Centre for Obesity Research and Epidemiology (CORE) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration