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Selenium in pregnancy intervention

Submission date 03/05/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/05/2013	**Overall study status** Completed	
Last Edited 18/12/2015	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Pre-eclampsia (condition causing high blood pressure and significant amounts of protein in the urine) is a major complication of pregnancy which can adversely affect mother and baby. At present there is no treatment except ending the pregnancy, which is difficult to do when babies are very premature. Selenium is an essential mineral of all diets. We have evidence that more than a small proportion of people living in the UK are partially deficient in selenium. Those who are young women are more liable to get pre-eclampsia when they get pregnant. In this pilot study we are testing the effect of small supplements of selenium to bring the daily intake to the recommended daily intake during pregnancy. We are asking 200 volunteers in their first pregnancies to enter a trial: half the women receive the daily supplement and the other half get a dummy tablet. Blood and other tests taken through pregnancy are designed to show whether or not the response to receiving the supplement changes the test results in a direction that favours not getting pre-eclampsia. If this is so, a much bigger study would be justified, which might lead to reasonable reduction in the disorder by a simple and safe dietary supplement.

Who can participate?
Women who are 12-14 weeks pregnant with their first baby visiting the John Radcliffe Hospital for a 12-week pregnancy scan will be approached to see if they wish to enter the trial. They are not eligible if under 18 years old, current smokers, taking any supplement containing selenium, taking thyroid medication, multiple pregnancy, abnormal ultrasound scan, chronic protein in the urine, heparin treatment, HIV, Hepatitis-B or Hepatitis-C positive, yeast intolerance (supplement contains yeast), inability or refusal to give informed consent.

What does the study involve?
The study will have two treatment groups: 60 mcg/day of selenium as selenium-enriched yeast or placebo (dummy) yeast (60 mcg/day is the recommended intake for UK pregnant women). Women will be randomly allocated to either treatment. A blood sample will be taken from all recruits at trial entry. Some blood will be used to measure selenium concentration. The remainder will be banked, along with a urine sample for later analysis. If separate, explicit, consent has been given for a blood sample for genetic analysis, an additional 5 ml of blood will be taken as part of the same procedure. Information will be recorded by the trial midwife to include:- blood pressure, date of last period, weight, height, ethnicity, family history of pre-eclampsia, chronic illness e.g. chronic hypertension, diabetes, thyroid disease, current medication, presence of severe morning sickness, smoker/non-smoker, alcohol use, vegetarian

or not. Women will be given a simple food frequency questionnaire to complete and a further questionnaire about dietary supplements taken which may be filled in at home. At week 20, women will again attend the John Radcliffe Hospital for a scan and at 34-36 weeks, they will be seen by the research midwife either at the hospital or at their homes. Blood and urine samples will be taken at 20 and 35 weeks and banked for measurement of different components that may be related to the risk of pre-eclampsia.

What are the possible benefits and risks of participating?
There is no benefit to the woman herself from enrolling but her participation may help women in the future to have a lower risk of pre-eclampsia as a result of what the study shows. The dose of selenium given is a nutritional dose and is the recommended intake of selenium for women. There are no risks of supplementation with selenium at this level. Women in many countries have a considerably higher intake than this.

Where is the study run from?
The study is run from the University of Surrey but women are recruited and followed up at the John Radcliffe Hospital in Oxford, a known centre of excellence for pre-eclampsia.

When is the study starting and how long is it expected to run for?
The study started on 16 February 2009 and recruited up until July 2011. Analysis of the information gathered from the trial is still ongoing.

Who is funding the study?
The Wellcome Trust (UK).

Who is the main contact?
Professor Margaret Rayman
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Contact information

Type(s)
Scientific

Contact name
Prof Margaret Rayman

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SPRINT version 5

Study information

Scientific Title
Selenium in PRegnancy INTervention: a double-blind, randomised, placebo-controlled, two-group study

Acronym
SPRINT

Study objectives
A small increase in selenium (Se) intake in pregnant women of inadequate Se status will protect against:- pre-eclampsia risk (as assessed by biomarkers), inflammation, oxidative stress, endothelial activation and placental dysfunction by increasing Se status and selenoprotein concentration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Milton Keynes REC, 11/12/2008, ref no 08/H0603/46

Study design
Double-blind randomised placebo-controlled two-group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Pre-eclampsia

Interventions

Two treatment groups: 60 mcg/day of selenium as selenium-enriched yeast or placebo yeast (60 mcg/day is the recommended intake for UK pregnant women).

Total duration of intervention: From randomisation (at 12 - 14 weeks gestation) until delivery.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Selenium supplement

Primary outcome measure
Plasma soluble fms-like tyrosine kinase-1 (sFlt-1) concentration. Measured in samples taken at 35 weeks gestation.

Secondary outcome measures
Plasma concentrations of: placental growth factor (PlGF), sEndoglin, ActivinA, InhibinA, E-selectin, vascular cell adhesion molecule 1 (VCAM-1), 3-Nitrotyrosine, Pentraxin 3, C-reactive protein (CRP). Measured in samples taken at 35 weeks gestation.

Overall study start date
16/02/2009

Completion date
15/02/2014

Eligibility

Key inclusion criteria
1. First pregnancy
2. 12-14 weeks pregnant at randomisation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200 (230 recruited to allow drop-out rate of 15%)

Key exclusion criteria
1. Under 18 years old
2. Current smokers (who have lower risk of pre-eclampsia)

3. Taking any supplement containing Se
4. Taking thyroid medication
5. Multiple pregnancy
6. Abnormal fetal anomaly scan
7. Chronic proteinuria
8. Heparin treatment
9. Human immunodeficiency virus (HIV), Hep-B or Hep-C positive
10. Yeast intolerance (supplement contains yeast)#
11. inability or refusal to give informed consent (the genetic component of the trial will be omitted in those who do not give explicit consent to this aspect of the trial)

Date of first enrolment
16/02/2009

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Surrey
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
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Sponsor type
University/education

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ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) grant ref: 083918/Z/07/Z

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/07/2014		Yes	No
Results article	results	01/06/2015		Yes	No
Results article	results	01/01/2016		Yes	No