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SPRING: Southampton pregnancy intervention for the next generation

Submission date
01/08/2013

Recruitment status
Suspended

Registration date
12/09/2013

Overall study status
Completed

Last Edited
05/05/2020

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Mothers nutritional status influences the growth and development of infants during pregnancy and after birth, and growth and development at these stages in life will improve bone growth and influence risk of long-lasting conditions such as heart disease and obesity in adulthood. Studies have shown that women of childbearing age from disadvantaged backgrounds are more likely to have a poor diet, and that those with the least healthy diets were found to be less likely to follow a good infant feeding pattern. It is also found that one third of women have insufficient vitamin D in late pregnancy, which can affect their childrens fat and bone mineral content. This study aims to find out whether a behaviour change intervention given by nurses and aimed at improving lifestyle during pregnancy will help improve a vitamin D supplementation intervention and have a positive effect on maternal and infant health.

Who can participate?
Pregnant women who are 18 years and over will be eligible if they attend the participating hospital for nuchal translucency or dating scans between 9 and 17 weeks of pregnancy and are aiming to give birth at a local maternity hospital.

What does the study involve?
A research nurse will approach women at their screening or dating scan visits, screen them for eligibility and gain written informed consent. At their first visit at 14 weeks, body measurements and a blood sample will be taken and they will be chosen, at random, to receive either vitamin D tablets or placebo (dummy) tablets to be taken during the study. Neither they nor the nurse will know which they are taking. They may also be chosen, at random, to have additional support from the nurse to explore in a conversation how to have a healthy pregnancy, and to set some goals for health behaviour change. At 19 weeks women will have a routine NHS ultrasound scan and a research ultrasound scan. Those in the behaviour change group will be engaged in a second conversation and review of progress with their goals. At 26 weeks, a nurse will phone the women to check on the progress of the pregnancy and confirm the date of the next appointment. Those in the behaviour change group will be engaged in a third conversation and review of progress. At 34 weeks, women will have an extra 3D ultrasound scan, fill in a questionnaire and measurements taken at 14 weeks will be repeated. Those in the behaviour change group will be engaged in a fourth conversation and review of progress. At birth, when

the women have had their babies, the midwife will collect samples from the placenta and the cord. Women will be invited to bring their babies for a bone scan and body measurements. A month after birth, a nurse will visit participants at home to discuss the health and well-being of the mother and their children. Those in the behaviour change condition will be engaged in a final conversation and review of goals. All mothers will be asked if they are prepared to be contacted again in the future to follow-up their babies as they grow.

What are the possible benefits and risks of participating?
Women will have 3D ultrasound scans of their babies, receive prints from the scan and an assessment of their baby's bone mass. These are not freely available to women under routine NHS care. Participants in the behaviour change group will be offered an opportunity to discuss issues arising with their pregnancy and skilled support in making changes to their lives and habits. This may lead to lasting improvements in their health and well-being, and in that of their child. The infant and childhood bone scan is associated with a low dose of radiation exposure, but this is equivalent to 2 days background radiation in Cornwall or 6 days in the UK generally. There is a possible and very small risk of asthma in children born to mothers in the top levels of vitamin D. The dose of vitamin D supplementation will bring women just into the normal range, to avoid over dosage. If the conversations cause distress, they will be stopped. All research staff are equipped with a list of helpline numbers so that participants can be referred to the appropriate service should it be necessary.

Where is the study run from?
Princess Anne Maternity Hospital, Southampton (UK)

When is the study starting and how long is it expected to run for?
October 2013 to October 2022

Who is funding the study?
The Medical Research Council, University Hospital Southampton NHS Foundation Trust, and NIHR Nutrition Biomedical Research Centre, Southampton (UK)

Who is the main contact?
Professor Cyrus Cooper
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2013-002854-66

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
452623v.1

Study information

Scientific Title
Randomised controlled trial of an intervention to improve the diets, lifestyles and body composition of pregnant women and their offspring

Acronym
SPRING

Study objectives
Lifestyle support in pregnancy improves maternal vitamin D levels and body composition assessed by dual energy x-ray absorptiometry (DXA) at birth, in infants born to women who have been randomised to receive vitamin D supplements or placebo, and further randomised to receive behaviour change support in pregnancy by trained nurses or to receive usual care. It is an investigator-initiated translational study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hampshire B, 12/09/2013, ref: 13/SC/0409

Study design
Phase II randomised controlled trial with process evaluation

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Musculoskeletal

Interventions
Women attending the Princess Anne Hospital for dating scans will be recruited and randomised to receive vitamin D or a placebo, and further randomised to receive support from nurses trained in supporting women to change their health behaviours or to receive usual care. There will therefore be four groups of participants:
1. Vitamin D supplemented plus usual care
2. Placebo plus usual care
3. Vitamin D supplemented plus behaviour change support
4. Placebo plus behaviour change support.
Randomisation to vitamin D or placebo will be blinded. This is not possible for randomisation to the behaviour change condition. Women are likely, however, to be unaware of their intervention status. All women will have contact with the research team at four time points during pregnancy. Obstetric details will be recorded at birth, and mothers and babies will be visited one month post-natally. Vitamin D levels, body composition, lifestyle and psychosocial outcomes in women and children will be compared across the four groups.

Intervention Type
Mixed

Primary outcome measure
Current primary outcome measures as of 15/06/2018:
1. Maternal circulating plasma 25(OH) vitamin D concentration at 34 weeks' gestation
2. Maternal diet quality at 34 weeks' gestation assessed with a 20-item food frequency questionnaire

Previous primary outcome measures as of 30/05/2018:
1. Maternal circulating plasma 25(OH) vitamin D concentration at 34 weeks
2. Maternal diet quality at 34 weeks gestation assessed with a 20-item food frequency questionnaire

Previous primary outcome measures:
1. Vitamin D status of mother measured by assay at baseline and again at 34 weeks of pregnancy
2. Body composition of infants at birth measured by DXA scan

Secondary outcome measures
Current secondary outcome measures as of 15/06/2018:
1. Women's level of self-efficacy at 34 weeks' gestation, assessed with the General Self-Efficacy scale
2. Pregnancy weight gain assessed by gain in weight between recruitment and 34 weeks' gestation

3. Maternal diet quality 1 month after birth
4. Breastfeeding status 1 month after birth (yes/no)
5. Neonatal whole body bone mineral content (BMC), lean and fat mass within 2 weeks after birth assessed by dual-energy X-ray absorptiometry (DXA)

Previous secondary outcome measures:
1. Maternal weight gain in pregnancy measured in kg at 14 and 34 weeks pregnancy
2. Rates of breastfeeding initiation and duration measured by questionnaire at 1 month after birth
3. Dietary quality of women measured by questionnaire and assay at 14 and 34 weeks of pregnancy
4. Self-efficacy measured by questionnaire at 14 and 34 weeks and 1 month after birth

Overall study start date
01/10/2013

Completion date
31/10/2022

Eligibility

Key inclusion criteria
Women attending the Princess Anne Hospital for nuchal lucency or dating scans in early pregnancy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
900

Key exclusion criteria
1. Women under the age of 18
2. Living outside a Southampton postcode area
3. Multiple pregnancy
4. Severely unwell
5. Allergic to peanuts or soya
6. Involved in another research study

Date of first enrolment
01/04/2014

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Southampton
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust (UK)

Sponsor details
Research and Development
SGH - Level E, Laboratory and Pathology Block,
SCBR - MP 138
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Research council

Funder Name

Medical Research Council (UK)

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

Funder Name
Added 03/07/2014:

Funder Name
NIHR Nutrition Biomedical Research Centre, Southampton (UK)

Results and Publications

Publication and dissemination plan
Planned publication of the first paper in June 2017 which will cover aspect of the process evaluation. The study results are expected to be available in December 2022.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
Anonymised data will be made available on request and will be stored at the MRC Lifecourse Epidemiology Unit, University of Southampton.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/10/2016		Yes	No
HRA research summary			28/06/2023	No	No