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Soy isoflavones on markers of bone turnover in females in the early menopause

Submission date
21/08/2012

Recruitment status
No longer recruiting

Registration date
05/09/2012

Overall study status
Completed

Last Edited
17/12/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims:
Soy (a vegetable foodstuff) contains chemicals called phyto-oestrogens (isoflavones) that have been shown to be of potential benefit to people during menopause as soy can alleviate menopausal hot flushes. It has also been shown that bones lose their density more rapidly during the immediate years following menopause. It is not really known if soy can have an effect on chemicals in the blood that reflects bone loss and growth. Therefore it is important to compare the effect of soy proteins, with and without phyto-oestrogens, on the bone health of women during this time.
This study aims to look at the effects of eating snack bars containing soy protein, with or without phyto-oestrogens, during the first two years of menopause. This will be done in such a way that neither the individual taking part, nor the investigator will know which type of bars the person has been eating.

Who can participate?
Women who have experienced menopause within the last 2 years

What does the study involve?
Participants will be asked to visit the research department a total of four times over a period of 6 months. They will also be contacted by telephone twice within this 6 month period. The first visit, that will last about 30 minutes, will involve discussing the study and signing a consent form. The subsequent visits will last around an hour.
1. At the second, third and final visit the participants will be asked to attend the clinic first thing in the morning, having fasted overnight. The blood samples will be tested for hormone levels and bone turn over makers.
2. At the second, third and final visit the participants will have an ultrasound scan examination of the lining of your womb.
3. At the second visit the participants will be given enough soy snack bars to eat twice a day (mid morning and mid afternoon) for 3 months.

What are the possible benefits and risks of participating?
Although there may be some direct benefits to some people taking part in the study, these will not be known until the study has finished. It is hoped that this study will help to provide the

information needed to inform the Food Standards Agency and UK governments regarding the safety and potential benefits of eating soy and phytooestrogens to women during menopause.

Where is the study run from?
The University of Hull at Brocklehurst Building of Hull Royal Infirmary.

When is study starting and how long is it expected to run for?
The study started in July 2010 and will end in December 2012

Who is funding the study?
Food Standard Agency, UK

Who is the main contact?
Prof Stephen Atkin
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Contact information

Type(s)
Scientific

Contact name
Prof Stephen Atkin

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol Version 2 date: 24/02/2012

Study information

Scientific Title

A double blind placebo controlled parallel trial of soy isoflavones on markers of bone turnover in females in the early menopause

Study objectives
Null hypothesis:
Neither soy protein alone (15g without isoflavones) or soy protein (15g) with isoflavones (66mg) will have an effect on either bone resorption or bone formation (i.e. bone turnover) in post menopausal women at the time of their greatest bone loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Humber Bridge Research Ethics Committee, 18/06/2010, ref: 10/H1304/5

Study design
Parallel double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Effect of soy phyto-eastrogens to people during menopause as soy have been shown to improve menopausal flusing symptoms.

Interventions
A bar containing 7.5g isolated soy protein powder (Solcon F) with 33mg of isoflavones (given twice daily) or 7.5g of the isolated soy (extracted, isoflavone free) protein alone (given twice daily) as control will be administered.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Change in bone turnover markers

Secondary outcome measures
1. Insulin resistance
2. Blood pressure
3. Lipid profile
4. Endothelial function
5. Changes in endometrial thickness

Overall study start date
29/09/2012

Completion date
12/12/2013

Eligibility

Key inclusion criteria
1. Women with a follicle-stimulating hormone (FSH) and luteinizing hormone (LH) greater than 20 mU/L and amenorrhoea for 1 year with or without vasomotor instability of hot flushing will be eligible to participate
2. Caucasian women

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Patients with liver dysfunction (ALT of greater than 135 u/L) or taking drugs that may interfere with liver function
2. Patients with impaired renal function (creatinine greater than 150, glomerular filtration rate less than 30)
3. Patients who have had antibiotic treatment within the last 6 months will also be ineligible for the study as antibiotics are known to change gut microflora and thus will interfere with phytoestrogen metabolism. This will also mean that patients who start taking antibiotics during the study will have to be withdrawn
4. Patients not wishing to allow disclosure to their GPs
5. Patients on any medication within 3 months of the study including steroid inhalers or HRT
6. Patients already self-supplementing with isoflavones
7. Vegetarian or vegans

Date of first enrolment

29/09/2012

Date of final enrolment
12/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull York Medical School
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
Daisy Building
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Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk/

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
Food Standard Agency (UK), ref: T10060

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	01/07/2018		Yes	No
Results article	results relating to thyroid hormone effects	22/11/2018		Yes	No