ISRCTN75939563 https://doi.org/10.1186/ISRCTN75939563

Phytoestrogen dietary supplementation in post-menopausal women with type two diabetes: effects on glycaemic control, insulin resistance and indices of cardiovascular risk. A cross over trial

Submission date	Recruitment status
16/11/2006	No longer recruiting
Registration date	**Overall study status**
14/12/2006	Completed
Last Edited	**Condition category**
18/12/2013	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol LREC 11/01/207

Study information

Scientific Title

Study objectives
The prevalence of type two diabetes in the UK is increasingly high. Most women with type two diabetes have an increased risk of cardiovascular diseases due to obesity, estrogen depletion, abnormal lipid profile, and endothelial dysfunction amongst others. Recent studies have suggested that dietary supplementation with soy protein combined with isoflavone have a beneficial effect in both glycaemic control and indices of cardiovascular risk. However, it remains unclear if this effect is due to soy protein or isoflavones. The aim of this study is clarify this.

Hypothesis:
Isoflavone supplementation alone has beneficial effects on glycaemic control, insulin resistance and cardiovascular risk factors in post-menopausal patients with diet controlled type two diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Yorkshire Local Ethics Committee, June 2002 (ref: LREC 11/01/207).

Study design
Cross over, double blind, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type two diabetes in post-menopausal women

Interventions
A tablet containing 66 mg of soy isoflavones or an identical microcrystalline cellulose tablet (placebo) will be given twice daily.

The patients will receive either placebo/isoflavone tablet for three months and after a period of four weeks washout they receive the other (cross over trial) for a further three months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Soy isoflavones

Primary outcome measure
1. Modification of glycaemic parameters
2. Modification of indices of cardiovascular risk

Secondary outcome measures
1. Alteration in renal function
2. Alteration in endogenous sex hormones

Overall study start date
01/07/2002

Completion date
01/03/2004

Eligibility

Key inclusion criteria
1. Post-menopausal women (amenorrhoea for at least 12 months)
2. Type two diabetes on diet alone as a form of treatment

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
36

Key exclusion criteria
1. Secondary causes of impaired glucose tolerance such as hypercortisolemia
2. No hormone replacement or stopped at least six weeks prior recruitment
3. Uncontrolled hypothyroidism (if receiving thyroid hormone replacement, the patient should be euthyroid with Thyroid Stimulating Hormones [TSH] less than 5.0 mU/L)

4. Blood pressure more than 160/90 mmHg
5. Recent initiation of statin treatment/dose modification (less than four weeks)
6. Patients not wishing to allow disclosure to General Practitioners (GPs)

Date of first enrolment
01/07/2002

Date of final enrolment
01/03/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Diabetes Centre
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull University (UK)

Sponsor details
Medical Department
Brocklehurst Building
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England
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Sponsor type
University/education

Website
http://www.hull.ac.uk/

ROR

https://ror.org/04nkhwh30

Funder(s)

Funder type
University/education

Funder Name
This trial is internally funded by Hull University, Medical Department, Diabetes and Endocrinology (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2007		Yes	No