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A double-blind placebo-controlled parallel trial of soy phytoestrogens in patients with type 2 diabetes and borderline low testosterone levels

Submission date	Recruitment status	[X] Prospectively registered
19/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/04/2019	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
7962

Study information

Scientific Title
A double-blind placebo-controlled parallel trial of soy phytoestrogens in patients with type 2 diabetes and borderline low testosterone levels

Acronym
DRN 431 (Soy and testosterone in men with diabetes)

Study objectives
The aim of this study is to determine if 15 g of soy protein (isoflavone free) alone versus 15 g soy protein with 66 mg of isoflavones given in two daily divided doses, has an effect on testosterone levels in men who have borderline or subclinical (without symptoms) hypogonadism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 09/H1304/45

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Metabolic

Interventions
There will be a three month phase of treatment with either active (15 g soy protein with 66 mg phytoestrogen) or control (15 g soy protein alone). A bar containing 7.5 g isolated soy protein powder (Solcon F) with 33 mg of isoflavones (given twice daily) or 7.5 g of the isolated soy (extracted isoflavone free) protein alone (given twice daily) as control will be administered.

Follow-up length: 3 months

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Soy protein, phytoestrogen

Primary outcome(s)
Quantify the magnitude

Key secondary outcome(s))
Not provided at time of registration

Completion date

12/12/2013

Eligibility

Key inclusion criteria
1. Diagnosis of type 2 diabetes
2. Patients will be on stable medication for their diabetes, hypertension, lipids and gout (if appropriate) for 3 months prior to entry into the study
3. Age between 45 - 75 years at the start of the study, male only
4. Serum testosterone value of 12 nmol/L or less (normal range 1236 nmol/L) and who are symptom free will be eligible to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
200

Key exclusion criteria
1. Patients with concurrent illness or any medication in the last 3 months
2. Patients not wishing to allow disclosure to their GPs
3. Patients who are taking hormone replacement therapy
4. Patients who are currently or have taken antibiotics in the last 3 months
5. Hba1c at recruiting stage of greater than 9%
6. Vegetarians
7. Smokers
8. Patients with known food allergies

Date of first enrolment
10/06/2010

Date of final enrolment
12/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Brocklehurst Building
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (FSA) (UK)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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	01/12/2017		Yes	No
Results article	results relating to effect on thyroid hormone levels	22/11/2018		Yes	No
Other publications	follow-up analysis	11/04/2019		Yes	No