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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

**Contact name**
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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 |