

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

<b>Submission date</b> 19/05/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/04/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

GP practice

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Quantify the magnitude

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

10/06/2010

**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 12-36 nmol/L) and who are symptom free will be eligible to participate

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Male

**Target number of participants**

Planned sample size: 250; UK sample size: 250

**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**

England

United Kingdom

**Study participating centre**

**Brocklehurst Building**

Hull

United Kingdom

HU3 2RW

## **Sponsor information**

**Organisation**

Hull and East Yorkshire Hospitals NHS Trust (UK)

**Sponsor details**

Medical Research, Teaching and Day Surgery Building

Daisy Building

Castle Hill Hospital

Castle Road

Hull

England

United Kingdom

HU16 5JQ

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hey.nhs.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

## 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?
<a href="#">Results article</a>	results	01/12/2017		Yes	No
<a href="#">Results article</a>	results relating to effect on thyroid hormone levels	22/11/2018		Yes	No
<a href="#">Other publications</a>	follow-up analysis	11/04/2019		Yes	No