

A double-blind, placebo-controlled, crossover trial of soy phytoestrogens in patients with compensated hypothyroidism

Submission date

05/04/2006

Recruitment status

No longer recruiting

Registration date

09/05/2006

Overall study status

Completed

Last Edited

30/04/2019

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ 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

T05029

Study information

Scientific Title

A double-blind, placebo-controlled, crossover trial of soy phytoestrogens in patients with compensated hypothyroidism

Acronym

SOPHY

Study objectives

In patients with compensated hypothyroidism , the defined soy protein/isoflavone preparation will cause a further elevation of thyroid stimulating hormone with a concomitant fall in thyroxine.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Hull and East Riding Local Research Ethics Committee on 02/09/2004, (ref: LREC/03/04/044); REC also gave a favourable ethical opinion on 13/02/06 for the extension of an additional study site in York

Study design

Double-blind, placebo-controlled crossover 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

Compensated hypothyroidism

Interventions

Soy protein alone versus soy protein with isoflavone in patients with compensated hyperthyroidism

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Soy protein with isoflavone

Primary outcome measure

Change in thyroid stimulating hormone (TSH) and thyroxine levels as in hypothesis

Secondary outcome measures

Not provided at time of registration

Overall study start date

10/04/2006

Completion date

10/02/2007

Eligibility

Key inclusion criteria

Patients with newly diagnosed compensated hypothyroidism (thyroid stimulating hormone [TSH] >4.7 and normal T4)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

134

Total final enrolment

60

Key exclusion criteria

1. Patients on thyroxine or drugs that interfere with thyroid function
2. Patients who have had antibiotics within 3 months of starting the trial
3. Patients not wishing to allow disclosure to their general practitioners (GPs)

Date of first enrolment

10/04/2006

Date of final enrolment

10/02/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Michael White Diabetes Centre

Hull

United Kingdom

HU3 2RW

Sponsor information

Organisation

Hull and East Yorkshire Hospitals Trust (UK)

Sponsor details

Anlaby Road

Hull

England

United Kingdom

HU2 3JZ

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abc@email.com

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01b11x021>

Funder(s)

Funder type

Government

Funder Name

Food Standards Agency

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?
Results article	results	01/05/2011		Yes	No
Other publications	follow-up analysis	11/04/2019		Yes	No