ISRCTN55827330 https://doi.org/10.1186/ISRCTN55827330

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

Submission date	Recruitment status
05/04/2006	No longer recruiting
Registration date	**Overall study status**
09/05/2006	Completed
Last Edited	**Condition category**
30/04/2019	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
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
-
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