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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
[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

Protocol serial number
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

Study type(s)
Treatment

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

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Michael White Diabetes Centre
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals Trust (UK)

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

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