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Cross-over randomised trial of adult hypothyroidism screening

Submission date	Recruitment status
29/01/2009	No longer recruiting
Registration date	**Overall study status**
10/02/2009	Completed
Last Edited	**Condition category**
09/11/2011	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

Contact name
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Additional identifiers

Protocol serial number
CTHS02

Study information

Scientific Title
A double blind randomised cross-over trial to assess the value of screening an adult population for hypothyroidism

Acronym

HSS

Study objectives
People detected with high thyroid stimulating hormone (TSH) through general screening respond symptomatically to thyroxine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire Research Ethics Committee A gave approval on the 7th June 2005 (ref: 05/Q1604 /67)

Primary study design
Interventional

Study design
Single centre double-blind randomised cross-over trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary hypothyroidism

Interventions
Each participant was allocated in random sequence to take thyroxine and placebo capsules, each for four months. During the thyroxine phase, participants started at a daily dose of 50 µg and this dose was increased by 25 µg per month until the serum TSH concentration fell below a pre-specified value of 2.0 mU/L.

Contact details for Joint Principal Investigator:
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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Thyroxine

Primary outcome(s)
To determine how many participants feel better when taking thyroxine than placebo according to their own self-assessment, asked at the end of the 8 month trial.

Key secondary outcome(s)
To assess the effects of thyroxine on:
1. General health
2. Symptom scores
3. Quality of life questionnaires
4. Cognitive function
5. Serum lipids

Measured at the start of the study and at the end of the four month thyroxine and placebo phases.

Completion date
31/05/2008

Eligibility

Key inclusion criteria
1. Women aged from 35 - 79 years, men aged from 65 - 79 years
2. Attended general screening at BUPA Wellness Centres between 1 January 2006 and 15 September 2007
3. Detected with thyroid stimulating hormone (TSH) greater than 4.0 mU/L

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. People under current clinical surveillance for thyroid disease, or taking thyroxine, or having known pituitary or adrenal disease
2. People known to have coronary artery disease
3. People with any illness that in the doctor's opinion warranted exclusion from the trial
4. Diabetics taking insulin or oral hypoglycaemics, or people taking anticoagulants (warfarin or

phenindinone)
5. People taking certain drugs that affect the serum concentration of TSH or free thyroxine

Date of first enrolment
01/02/2006

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wolfson Institute of Preventive Medicine
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation
Queen Mary University of London (UK)

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
BUPA Foundation (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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	01/06/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes