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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at: http://www.wolfson.qmul.ac.uk/hssleaflet/hssleaflet.pdf

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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Scientific contact for the trial:
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Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
01/02/2006

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

Age group
Adult

Sex
Both

Target number of participants
60

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
England

United Kingdom

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

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details

c/o Professor Malcolm Law
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Sponsor type
Research organisation

Website
http://www.qmul.ac.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

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	01/06/2010		Yes	No