

Cross-over randomised trial of adult hypothyroidism screening

Submission date

29/01/2009

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

10/02/2009

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

09/11/2011

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Malcolm Law

Contact details

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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)

Study design

Single centre double-blind randomised cross-over trial

Primary study design

Interventional

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