

# Cross-over randomised trial of adult hypothyroidism screening

**Submission date**

29/01/2009

**Recruitment status**

No longer recruiting

**Registration date**

10/02/2009

**Overall study status**

Completed

**Last Edited**

09/11/2011

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ 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**

Wolfson Institute of Preventive Medicine  
Queen Mary University of London  
Charterhouse Square  
London  
United Kingdom  
EC1M 6BQ

## 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:

Professor Sir Nicholas Wald

Wolfson Institute of Preventive Medicine

Barts and The London, Queen Marys School of Medicine

Charterhouse Square

London

EC1M 6BQ  
Email: n.j.wald@qmul.ac.uk

Scientific contact for the trial:  
Dr Munir Abu-Helalah  
Wolfson Institute of Preventive Medicine  
Queen Mary University of London  
Charterhouse Square  
London EC1M 6BQ  
United Kingdom  
Email: moneeraq@hotmail.com

### **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 phenindione)
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  
Wolfson Institute of Preventive Medicine  
Charterhouse Square  
London  
United Kingdom  
EC1M 6BQ

**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?
<a href="#">Results article</a>	results	01/06/2010		Yes	No