

# Subclinical hypothyroidism (SCH), cardiovascular risk and quality of life

**Submission date**  
19/09/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
19/10/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
09/11/2022

**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**  
Dr Jolanta Weaver

**Contact details**  
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Sheriff Hill  
Gateshead  
United Kingdom  
NE9 6SX

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
199/MED

## Study information

**Scientific Title**

Subclinical hypothyroidism (SCH), cardiovascular risk and quality of life

**Study objectives**

The cardiovascular risk in people with SCH, health status and quality of life can be improved by treatment with L-thyroxine.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Double blind randomised controlled crossover study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Subclinical hypothyroidism

**Interventions**

Double blind randomised controlled crossover study using thyroxine (100 mcg/day) versus placebo.

**Intervention Type**

Drug

**Phase**

Not Specified

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

L-thyroxine

**Primary outcome measure**

Improvement in brachial artery Flow Mediated Dilatation (FMD) as a marker of vascular endothelial function and Total Cholesterol (TC) levels, after 12 weeks of L-thyroxine treatment.

**Secondary outcome measures**

Changes in:

1. Health status
2. Quality of life
3. Weight as assessed by body mass index
4. Waist circumference and waist hip ratio
5. Blood pressure
6. Triglyceride
7. High Density Lipoprotein (HDL) cholesterol
8. Low Density Lipoprotein (LDL) cholesterol
9. Apolipoprotein A1 and apolipoprotein B
10. Serum markers of endothelial function (e-selectin, soluble adhesion molecule 1, tissue plasminogen activator and plasminogen activator inhibitor 1) and markers of inflammation high sensitive C-reactive protein

**Overall study start date**

01/02/2003

**Completion date**

10/01/2005

## Eligibility

**Key inclusion criteria**

1. Subjects from Primary Care (general practices)
2. Aged 18 to 80 years of age
3. Who have at least two abnormal thyroid function tests

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100

**Total final enrolment**

100

**Key exclusion criteria**

1. Thyroid disease and its treatment
2. Medications that could cause thyroid hormone dysfunction
3. Diabetes mellitus
4. Renal failure (serum creatinine greater than 120  $\mu\text{mol/l}$ )

5. Vascular disease
6. Psychiatric conditions or its treatment
7. Current or previous pregnancy in the last two years

**Date of first enrolment**

01/02/2003

**Date of final enrolment**

10/01/2005

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Queen Elizabeth Hospital**

Gateshead

United Kingdom

NE9 6SX

## **Sponsor information**

**Organisation**

Gateshead Health NHS Foundation Trust (UK)

**Sponsor details**

Queen Elizabeth Hospital

Sheriff Hill

Tyne and Wear

Gateshead

England

United Kingdom

NE9 6SX

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.gatesheadhealth.nhs.uk/>

**ROR**

<https://ror.org/01aye5y64>

# Funder(s)

## Funder type

Charity

## Funder Name

NHS Research and Development (UK)

## Funder Name

Research Endocrine Fund (UK)

## Funder Name

Gateshead Diabetes Charitable Fund (UK)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## 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="#">Other publications</a>	See	01/05/2005		Yes	No
<a href="#">Results article</a>		01/05/2007		Yes	No