

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

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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?
Other publications	See	01/05/2005		Yes	No
Results article		01/05/2007		Yes	No