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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/10/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
09/11/2022	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

Queen Elizabeth Hospital Sheriff Hill Gateshead United Kingdom NE9 6SX

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 µmol/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

United Kingdom

England

Study participating centre Queen Elizabeth Hospital Gateshead

United Kingdom NE9 6SX

Sponsor information

Organisation

Gateshead Health NHS Foundation Trust (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

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