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

Submission date	Recruitment status	[_] Prospectively registered
19/09/2005	No longer recruiting	[_] 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

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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

Primary study design
Interventional

Study design
Double blind randomised controlled crossover study

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		01/05/2007		Yes	No
Other publications	See	01/05/2005		Yes	No