

Stem cells in subclinical hypothyroidism

Submission date 09/09/2009	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 16/09/2009	Overall study status Completed	☐ Protocol
Last Edited 05/08/2022	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ 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

Protocol serial number
05/Q090/104

Study information

Scientific Title
The role of circulating endothelial progenitor cells in relation to endothelial dysfunction in subclinical and overt hypothyroidism

Study objectives

The number of circulating endothelial progenitor cells is reduced in subclinical and overt hypothyroidism.

The circulating endothelial progenitor cells in subclinical and overt hypothyroidism can be improved after thyroxine therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Gateshead and South Tyneside Local Research Ethics Committee, approved on 12/03/2007 (ref: 05/Q0901/104)

Study design

Interventional open-label single-arm trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypothyroidism

Interventions

Thyroxine dose 100 mcg (open label tablet) per day, dose adjusted if required.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Thyroxine

Primary outcome(s)

Number and function of endothelial progenitor cells.

All outcomes will be assessed before and after thyroxine therapy (being stable for 3 months on therapy).

Key secondary outcome(s)

Flow mediated dilatation.

All outcomes will be assessed before and after thyroxine therapy (being stable for 3 months on therapy).

Completion date

30/11/2009

Eligibility

Key inclusion criteria

1. Both males and females, age less than 70
2. Patients with confirmed subclinical hypothyroidism (thyroid-stimulating hormone [TSH]<10 mU/L) and overt hypothyroidism (TSH>10 mU/L)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Total final enrolment

20

Key exclusion criteria

1. Treatment for thyroid conditions
2. Known cardiovascular disease or risk factors

Date of first enrolment

01/05/2007

Date of final enrolment

30/11/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Newcastle University

Gateshead

United Kingdom

NE9 6SX

Sponsor information

Organisation

Gateshead Health NHS Foundation Trust (UK)

ROR

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

Funder(s)

Funder type

Government

Funder Name

Gateshead NHS R and D and Gateshead Diabetes Research 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	results	01/01/2010		Yes	No
Results article	subclinical thyrotoxicosis and cardiovascular risk results	18/07/2022	05/08/2022	Yes	No