Stem cells in subclinical hypothyroidism

Submission date	Recruitment status No longer recruiting	Prospectively registered		
09/09/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/09/2009	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
05/08/2022	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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 overthypothyroidism.

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

Secondary study design

Other

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Number and function of endothelial progenitor cells.

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

Secondary outcome measures

Flow mediated dilatation.

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

Overall study start date

01/05/2007

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

Age group

Other

Sex

Both

Target number of participants

60

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

Locations

Countries of recruitment

England

NE9 6SX

United Kingdom

Study participating centre Newcastle University Gateshead United Kingdom

Sponsor information

Organisation

Gateshead Health NHS Foundation Trust (UK)

Sponsor details

Sheriff Hill
Gateshead
Tyne and Wear
Gateshead
England
United Kingdom
NE9 6SX
+44 (0)191 445 2181
J.U.Weaver@ncl.ac.uk

Sponsor type

Hospital/treatment centre

Website

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

ROR

https://ror.org/01aye5y64

Funder(s)

Funder type

Funder Name

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