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Stem cells in subclinical hypothyroidism

Submission date	Recruitment status	[_] Prospectively registered
09/09/2009	No longer recruiting	[_] 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

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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 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

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

30/11/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
Gateshead Health NHS Foundation Trust (UK)

Sponsor details
Sheriff Hill
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Sponsor type
Hospital/treatment centre

Website
http://www.gatesheadhealth.nhs.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

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