ISRCTN70334066 https://doi.org/10.1186/ISRCTN70334066

Stem cells in subclinical hypothyroidism

Submission date
09/09/2009

Recruitment status
No longer recruiting

Registration date
16/09/2009

Overall study status
Completed

Last Edited
05/08/2022

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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