# Stem cells in subclinical hypothyroidism

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
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

Dr Jolanta Weaver

#### Contact details

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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
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes