

# Levothyroxine and selenium effect on endothelial progenitor cells count in hypothyroid subjects

<b>Submission date</b> 06/08/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 05/09/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/09/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The thyroid gland is a small gland found in the neck that produces two hormones, thyroxine and triiodothyronine, to help regulate the body's metabolism. Hypothyroidism is a medical condition where the thyroid gland doesn't produce enough of these hormones, causing many of the body functions to slow down. Symptoms of the condition include feeling tired and cold, gaining weight, difficulty concentrating and feeling depressed. It is also linked to an increased risk of cardiovascular (for example, heart) disease and oxidative stress. Endothelial Progenitor Cells (EPC) are cells that help regenerate the inner lining (endothelial layer) of blood vessels. They represent a well know marker of cardiovascular risk. The lower the EPC count the higher is the cardiovascular risk. Recent studies have demonstrated that EPC count is reduced in patients suffering from subclinical (without symptoms) hypothyroidism, and that replacement hormone treatment with Levothyroxine is able to restore an EPC count at similar levels to normal. It can therefore be speculated that low EPC count may contribute to the increased cardiovascular risk seen in people with hypothyroidism. One of the aim of this study is to evaluate EPC count either in subclinical hypothyroidism, or in overt (with symptoms) hypothyroidism and see whether there is a link between hypothyroidism and low EPC count. Blood pressure, and blood glucose and lipid levels are also measured to assess patients' metabolic profile. The other aim of the study is to test the hypothesis that treatment with Levothyroxine is able to restore a normal EPC count in people with hypothyroidism. As already mentioned, hypothyroidism is also a condition characterized by increased oxidative stress, and Selenium, a trace element that is involved in thyroid function and thyroid hormones metabolism, has been shown to have anti-oxidant activity. With this in mind, we also test the hypothesis that Selenium, thanks to its anti-oxidant activity, may have a role in hypothyroid EPC count.

### Who can participate?

Adults with hypothyroidism.

### What does the study involve?

Participants are randomly allocated into one of 4 groups. Those in group 1 are given Levothyroxine once a day. Those in group 2 are given 83 mg of Selenium once a day. Those in

group 3 are given 166 mg of Selenium once a day. Those in group 4 are given 249 mg of Selenium once a day. All participants have thyroid function tests and EPC count tests at the start of the study and 3 months later. Participants in group 1 have an additional thyroid function test 45 days after starting their treatment to adjust the dose of Levothyroxine if required.

What are the possible benefits and risks of participating?  
Not provided at time of registration.

Where is the study run from?  
V. Fazzi Hospital (Italy)

When is the study starting and how long is it expected to run for?  
May 2015 to July 2015

Who is funding the study?  
V. Fazzi Hospital (Italy)

Who is the main contact?  
Dr Roberto Negro  
robnegro@tiscali.it

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Roberto Negro

**ORCID ID**  
<http://orcid.org/0000-0001-9282-4530>

**Contact details**  
Piazza F. Muratore  
Lecce  
Italy  
73100  
+390832661680  
robnegro@tiscali.it

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Levothyroxine and selenium effect on endothelial progenitor cells count in hypothyroid subjects: an interventional single centre trial

## Study objectives

To test the impact of levothyroxine or selenium in endothelial progenitor cells count in hypothyroid patients

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Interventional single-centre trial

## Primary study design

Interventional

## Secondary study design

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Endothelial progenitor cells in hypothyroid patients

## Interventions

The study has four treatment arms:

1. First arm, hypothyroid patients received Levothyroxine (once a day)
2. Second arm hypothyroid patients received Selenium 83 mg (once a day)
3. Third arm hypothyroid patients received Selenium 166 mg (one a day)
4. Fourth arm hypothyroid patients received Selenium 249 mg (once a day)

Thyroid function test were checked 45 days after initiation treatment to adjust the dose of Levothyroxine. In all the four arms thyroid function test end Endothelial Progenitor Cell count are checked at baseline and three months later.

## Intervention Type

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

1. Levothyroxine 2. Selenium

**Primary outcome measure**

EPC count in hypothyroid patients before and three months after treatment

**Secondary outcome measures**

Anthropometric and biochemical measures before and after treatment

**Overall study start date**

01/05/2015

**Completion date**

31/07/2015

**Eligibility****Key inclusion criteria**

Hypothyroid patients having TSH>4.5mIU/L and <20mIU/L

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100

**Total final enrolment**

100

**Key exclusion criteria**

1. Cardiovascular disease
2. Diabetes
3. Hypertension
4. Drugs interfering with EPC count

**Date of first enrolment**

01/05/2015

**Date of final enrolment**

31/07/2015

# Locations

## Countries of recruitment

Italy

## Study participating centre

V. Fazzi Hospital

Lecce

Italy

73100

# Sponsor information

## Organisation

V. Fazzi Hospital

## Sponsor details

Piazza F. Muratore

Lecce

Italy

73100

## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/04fvmv716>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

V. Fazzi Hospital (Italy)

# Results and Publications

## Publication and dissemination plan

The aim is to be published in a peer reviewed endocrine journal.

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2016	02/09/2020	Yes	No