

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

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

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

EPC count in hypothyroid patients before and three months after treatment

Key secondary outcome(s)

Anthropometric and biochemical measures before and after treatment

Completion date

31/07/2015

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

V. Fazzi Hospital (Italy)

Results and Publications

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?
Results article	results	01/07/2016	02/09/2020	Yes	No