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

Submission date
06/08/2015

Recruitment status
No longer recruiting

Registration date
05/09/2015

Overall study status
Completed

Last Edited
02/09/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. Hose 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?
Results article	results	01/07/2016	02/09/2020	Yes	No