Microcirculatory and macrocirculatory alterations in different thyroid states

Published: 24-11-2014
Last updated: 20-04-2024

To assess the changes in cardiac function and the microcirculatory function in different thyroid states. We aim to identify how thyroid state affects changes in micro and macro hemodynamics.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON40419

Source
ToetsingOnline

Brief title
Microcirculation in different thyroid states

Condition

- Cardiac disorders, signs and symptoms NEC
- Thyroid gland disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cardiac function, microvasculature

Research involving
Human

Sponsors and support

Primary sponsor: endocrinologie
Source(s) of monetary or material Support: NWO

Intervention

Keyword: cardiac output, microvasculature, thyroid cancer, thyroid state

Outcome measures

Primary outcome

changes in cardiac function (cardiac output and mean arterial bloodpressure)

and microcirculatory function (as measured with Cytocam) in different thyroid

states.

Secondary outcome

• Capillary refill time

• Skin-difference temperature gradient (Tskin-diff)

• Peripheral perfusion index (PI)

• Transthoracic cardiac ultrasound

• Heart rate

Study description

Background summary

Hypothyroidism is a common disorder affecting ~4.5% of the population. Despite adequate restoration of biochemical euthyroidism (defined as normal levels of Thyroid Stimulating Hormone (TSH) and thyroxine (T4)), a significant number of patients have persistent symptoms such as fatigue; muscle aches and diminished cognitive and psychological function. However, the cause of these persistent symptoms is unknown.
Normal thyroid hormone levels are required to maintain normal cardiovascular function. Important changes in cardiac structure and function have been reported in patients with overt and subclinical hypothyroidism. Endothelial dysfunction has also been reported in conduit arteries of patients with clinical and subclinical hypothyroidism. The microcirculation is the main site of oxygen delivery to tissue cells and is essential for the maintenance of cellular life and function. The function of the organs is directly dependent on the function of their respective microcirculation. The effects of thyroid

hormone deficiency on the microcirculation have not been assessed. The hypothesis is that changes in microcirculation and macrocirculation may well explain the variable symptoms in patients with biochemical euthyroidism.

Study objective

To assess the changes in cardiac function and the microcirculatory function in different thyroid states. We aim to identify how thyroid state affects changes in micro and macro hemodynamics.

Study design

Single centre, observational cohort study. Patients with differentiated thyroid cancer are treated with radioactive iodine as part of the cancer treatment after thyroidectomy and in case of residual or recurrent disease. These patients are subject to hypothyroidism (before I-131 therapy) followed by subclinical hyperthyroidism after reinitiating thyroid hormone. Therefore, patients with differentiated thyroid cancer provide an excellent model to study the consequences of variations in thyroid state. All patients who will be treated with radioactive iodine, will be approached for cardiac output measurement, cardiac ultrasound, assessment of the microcirculation and a 12-lead electrocardiogram.

Study burden and risks

Microcirculation and cardiac output assessment are non-invasive procedures and there are no risks associated with these monitoring devices. The assessment will take about 30 minutes and will take place during the regular clinical follow-up. The risks associated with participation are negligible. Subjects will be compensated with a VVV-voucher of 100 Euro per visit.

Contacts

Public
Selecteer

dr. molewaterplein 50
Rotterdam 3015 GE
NL
Scientific
Selecteer

dr. molewaterplein 50
Rotterdam 3015 GE

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with differentiated thyroid carcinoma who have to receive a treatment with radioactive iodine.
Has the capacity to understand and willingness to sign an informed consent form
Aged 18-80 years

Exclusion criteria

* Other malignancy
* Clinically relevant active systemic disease (such as autoimmune or infectious diseases)
* Pregnancy
* Heart failure (New York Heart Association (NYHA) classes II, III or IV)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-11-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL46357.078.14