Association of Graves' disease and thymic hyperplasia and the role of TSH receptor antibodies in T cell development

Published: 27-10-2008
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The aim of this study is to investigate how often thymic hyperplasia is present in Graves' disease. Moreover we will investigate if thymic hyperplasia in Graves' disease is caused by stimulation of T cell development in the thymus.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON35294

Source
ToetsingOnline

Brief title
Association of Graves' disease and thymic hyperplasia

Condition

- Other condition
- Thyroid gland disorders

Synonym
Hyperthyroidism

Health condition

thymus hyperplasie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Graves' disease, T cell development, thymic hyperplasia, Thymus

Outcome measures

Primary outcome

Presence of thymic hyperplasia.

Secondary outcome

Increase of naive T cells in the blood.

Increase in TRECs in the blood.

Study description

Background summary

Graves' disease is associated with thymic hyperplasia. Since it is known that the TSH receptor is also present in the thymus, stimulating antibodies against the TSH receptor could play a role in thymic hyperplasia. Moreover high concentrations of TSH are able to stimulate T cell development in vitro.

Study objective

The aim of this study is to investigate how often thymic hyperplasia is present in Graves' disease. Moreover we will investigate if thymic hyperplasia in Graves' disease is caused by stimulation of T cell development in the thymus.

Study design

30 patients with Graves' disease who will be treated with radioactive iodine therapy will be recruited on the nuclear medicine department. After the radioactive iodine scan according to the regular treatment, an extra scan will be made from the thymus. Moreover blood samples of these patients will be taken.

Study burden and risks

An extra scan will be made, which takes 10 minutes, there is no extra exposure to radiation since patients already recieved the radioactive iodine for their normal treatment. Moreover blood samples will be taken.

Participation to this study does not involve extra risks.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Graves' disease

radioactive iodine treatment

Exclusion criteria

use of corticosteroids
older than 50 years of age
psychiatric diseases
pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2009
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-02-2009
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-04-2010
Application type:	Amendment
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

ID: 25605
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL22657.078.08
OMON	NL-OMON25605