The role of TSH in the human immune system, a randomized, controlled, trial

Published: 20-07-2009
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The main objective of this study is to determine the role of TSH in the generation of new T cells by thymopoiesis

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immunodeficiency syndromes
Study type	Interventional

Summary

ID

NL-OMON33266

Source
ToetsingOnline

Brief title
The role of TSH in the human immune system

Condition

- Immunodeficiency syndromes

Synonym
T cell deficiency

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: T cell reconstitution, Thymus, TSH

Outcome measures

Primary outcome

The main endpoints of the study are a change in cell numbers or ratio*s of

peripheral T cell subpopulations and changes in thymic output measured by naïve

T cells and TREC analysis.

Secondary outcome

The secundary endpoints of the study are changes in lipid and bone metabolism,

CK levels and metabolomics

Study description

Background summary

TSH stimulates differentiation and inhibits cell death of thymocytes in vitro, in a fetal thymic organ culture. Therefore TSH could be a previously unrecognized growth and/or survival factor for thymocytes. In this study we want to further investigate the role of TSH in T-cell development in vivo

Study objective

The main objective of this study is to determine the role of TSH in the generation of new T cells by thymopoiesis

Study design

The study is a single center clinical trial

Intervention

Patients will receive 0.3mg rhTSH i.m. twice a week for 3 weeks

Study burden and risks

Increased TSH levels in hypothyroid patients and treatment of patient with thyroid cancer with recombinant TSH do not result in severe morbidity.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

hypothyroidism for the last 6 months with only thyroxin substitution therapy
T3, T4 and TSH blood levels within the normal range for the past 6 months
TSH>20 mU/l at diagnosis
Presence of anti TPO antibodies
Age 20-45 years

Exclusion criteria

Uncontrolled hypothyroidism
Presence of antibodies to the TSH receptor
History of M. Graves or thyroiditis

Presence of struma or an enlarged tyroid gland measured with ultrasound
Serious infections in the last 3 months
Thymectomy in the medical history
T cell affecting co-medication

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-03-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	thyrogen
Generic name:	recombinant human thyrotropin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	20-07-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	26-11-2009
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

ID: 20628
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2008-001827-76-NL
CCMO	NL28134.078.09
OMON	NL-OMON20628