De rol van het hormoon TSH in het immuunsysteem.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20628

Source
Nationaal Trial Register

Health condition

immunodeficiencies
T cell development

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam, The Netherlands
Source(s) of monetary or material Support: Erasmus Medical Center, Rotterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

Primary endpoint consist of a change in thymic output, peripheral cell numbers or ratio’s of peripheral T cell
subpopulations in response to treatment with rhTSH. T cell subpopulations will be defined using flow
cytometry. Moreover thymic output will be measured using TREC analysis.

Secondary outcome

Secondary endpoints are:

1. Lipid metabolism;

2. Bone metabolism;

3. CK levels;

4. Urine metabolites.

Study description

Background summary

TSH-R was found to be functionally expressed on thymocytes, able to stimulate T cell development in vitro. Therefore the aim of this study is to investigate if recombinant human TSH (rh-TSH) improves human T-cell development in vivo in a clinical setting, as a proof of concept for use of rh-TSH in a variety of diseases in which naïve T cell reconstitution is desirable.

10 patients in the age of 20-45 years stably treated for hypothyroidism will be included in this study. Patients will receive 0.3mg rhTSH i.m. twice a week for 3 weeks. Effects on the T cell pool will be measured using TREC and FACS analyses.

Study objective

TSH can act on thymocytes to enhance T cell development.

Study design

Visit 1: Information and screening;

Visit 2: Informed consent;

Visit 3: normal values, start trial medication (T=0d);

Visit 4: trial medication and small blood sample (T=3d);

Visit 5: trial medication blood samples (T=7d);

Visit 6: trial medication and small blood sample (T=10d);

Visit 7: trial medication and blood samples (T=14d);

Visit 8: Trial medication and small blood sample (T=17d);

Visit 9: Blood samples (T=21d);

Visit 10: Control evaluation, without trial medication (T=90d).

Intervention

All subjects will receive rhTSH (ThyrogenÒ) purchased from Genzyme Europe BV (The Netherlands,
Naarden) in a dose of 0.3mg twice weekly intramuscular for 3 weeks.

Contacts

Public
Dr. Molewaterplein 50-60
Kim Weerd, van der
Rotterdam 3015 GE
The Netherlands
+31 (0)10 7044651
Scientific
Dr. Molewaterplein 50-60
Kim Weerd, van der
Rotterdam 3015 GE
The Netherlands
+31 (0)10 7044651

Eligibility criteria

Inclusion criteria

1. Have the capacity to understand and willingness to sign an informed consent form;

2. Have been medically treated for primary hypothyroidism for the last 6 months with only thyroxin substitution therapy;

3. Adequate treatment with thyroxine;

4. Have medically controlled disease;

5. T3 and T4 blood levels within the normal range for the past 6 months;

6. TSH within the normal range for the past 6 months;

7. TSH>20 mU/l at diagnosis;

8. Presence of anti TPO antibodies;

9. Age 20-45 years.

Exclusion criteria

1. Uncontrolled hypothyroidism;

2. Presence of antibodies to the TSH receptor;

3. History of M. Graves or thyroiditis;

4. Presence of struma;

5. Enlarged tyroid gland measured with ultrasound;

6. Serious infections in the last 3 months;

7. Have current symptoms of cardiac disease;

8. Have current signs or symptoms of severe, progressive or uncontrolled renal, hepatic, hematologic,
gastrointestinal, endocrine, pulmonary, cardiac, neurologic, or cerebral disease;

9. Clinically relevant abnormal findings during routine physical examination, screening blood samples of
hematology, biochemistry, urinanalysis and/or known ECG abnormalities;

10. Alcohol abuse;

11. Known hematologic malignancy;

12. Known thyroid malignancy;

13. Other autoimmune disorders than hypothyroidism;

14. Thymectomy in the medical history;

15. T cell affecting co-medication.
Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-12-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33266
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2017
NTR-old	NTR2134
CCMO	NL28134.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33266

Study results

Summary results
N/A