De rol van het hormoon TSH in het immuunsysteem.

Gepubliceerd: 04-12-2009 Laatst bijgewerkt: 15-05-2024

TSH can act on thymocytes to enhance T cell development.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20628

Bron
Nationaal Trial Register

Aandoening

immunodeficiencies
T cell development

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Rotterdam, The Netherlands
Overige ondersteuning: Erasmus Medical Center, Rotterdam, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

TSH can act on thymocytes to enhance T cell development.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-12-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33266
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A