Relation between intestinal MICRObiota translocation and development of Graves Orbitopathy: the MICRO-GO study

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We aim to investigate whether a relation between intestinal microbiota composition, mucosal integrity and translocation of bacteria into adipose tissue of the affected eye is related to the severity of Graves orbitopathy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON41329

Source
ToetsingOnline

Brief title
MICRO-GO

Condition

- Thyroid gland disorders
- Ocular neuromuscular disorders

Synonym
eyedisease associated with hyperthyreoidism, Graves orbitopathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Graves hyperthyreoidism, gutmicrobiota, inflammation, orbitopathy

Outcome measures

Primary outcome

To determine differences in orbital tissue bacterial content and inflammatory genes expression is associated with clinical disease severity score (CAS) in Graves orbitopathy patients

Secondary outcome

Differences in gutmicrobiota composition, mucosal integrity, subsequent endotoxemia and plasma levels of inflammation between subjects with low and high CAS scores in patients with Graves orbitopathy

Study description

Background summary

Graves hyperthyreoidism (prevalencee 400 per 100,000, more females than males, age of onset between 20*50 years) is an autoimmune disease with undefined pathophysiology in which thyroid autoantibodies are produced against thyroid TSH-receptor thus inducing hyperthyroidism. In 10-15% of these cases Graves Orbitopathy develops due to influx of mononucleair cell (lymfocytic) infiltration in adipose tissue of the affected eye. recent articles have suggested a role for the intestinal microbiota composition in the development of Graves orbitopathy.

Study objective

We aim to investigate whether a relation between intestinal microbiota composition, mucosal integrity and translocation of bacteria into adipose tissue of the affected eye is related to the severity of Graves orbitopathy.

Study design

observational study

Study burden and risks

Based on the observational nature of this researchproposal we postulate that the studyburden is low and risk for participating patients will be nil.

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

Caucasian subjects with Graves orbitopathy (males/postmenopauzal females, aged 18 to 69 years-old; and not on concomitant medication besides block/replacement therapy (thyrax en strumazol/PTU))

Exclusion criteria

Use of prednisone/antibiotic in the last three months including proton pump inhibitors (PPI) is prohibited.

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):	25-09-2013
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	07-06-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL44564.018.13