EIS-GO: Early Identification of Steroid non-response in moderate severe active Graves* Orbitopathy, a prospective study

Published: 30-08-2022
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To determine the accuracy of predicting steroid responders and non-responders with a whole blood in vitro steroid sensitivity assay.

Ethical review	Approved WMO
Status	Pending
Health condition type	Eye disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON51784

Source
ToetsingOnline

Brief title
Improved diagnosis for GO

Condition

- Eye disorders NEC

Synonym
Graves' orbitopathy

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: ZonMW Programma Topspecialistische Zorg

en Onderzoek

Intervention

Keyword: Biomarkers, Graves orbitopathy, Steroid response

Outcome measures

Primary outcome

In vitro steroid sensitivity assay and clinical response to treatment with

intravenous steroids.

Secondary outcome

Secondary endpoints for clinical steroid respons (see protocol 8.1.2)

Quality of Life questionnaires

Study description

Background summary

Graves* orbitopathy (GO) is an uncommon autoimmune orbital inflammatory condition, which often results in a decrease in the quality of life due to disease sequelae, such as double vision and disfiguring proptosis. Standard immunosuppressive treatment for active GO consists of 12-week courses with intravenous steroids, but alternative drugs are available if there is insufficient response to treatment with steroids. Currently, we have no available assay nor a set of biomarkers to assess the sensitivity to steroids prior to such treatment. The aim of our study is to assess the use of an in vitro steroid sensitivity assay to predict response to treatment with intravenous steroids. Also, we will assess which biomarkers in peripheral blood and/or tear fluid reflect steroid sensitivity. Thereby, a more efficacious and precise treatment may become available for patients with active GO. This may reduce the patients* disease burden and improve their quality of life.

Study objective

To determine the accuracy of predicting steroid responders and non-responders with a whole blood in vitro steroid sensitivity assay.

Study design

Prospective observational, and analysis of protein biomarkers.

Study burden and risks

Participants do not benefit, risks are negligible, burden is low.

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

Active, moderate-severe GO.

Exclusion criteria

Treatment with steroids or other immunomodulating drugs in the past 3 months.
Contra-indication for intravenous methyl prednisone (IVMP).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2022
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-08-2022
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

No registrations found.

In other registers

Register	ID
CCMO	NL81156.078.22