The pathogenesis and prognostic factors of scleritis

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ocular infections, irritations and inflammations
Study type	Observational invasive

Summary

ID

NL-OMON55201

Source
ToetsingOnline

Brief title
The pathogenesis of scleritis

Condition

- Ocular infections, irritations and inflammations
- Autoimmune disorders

Synonym
Scleritis; inflammation of the sclera

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,Stichting Lijf en Leven

Intervention

Keyword: Autoantibodies, Biomarkers, Pathogenesis, Scleritis

Outcome measures

Primary outcome

The main study parameter is the difference in prevalence of specific

auto-antibodies between patients with scleritis and controls.

Secondary outcome

Other study parameters are the differences between presence of MMPs, specific

biomarkers and HLA associations between patients and controls.

Study description

Background summary

The pathogenesis of scleritis, a severe and potentially blinding inflammation of the sclera, is still not unravelled. Scleritis is often associated with severe (autoimmune) systemic disorders and it was suggested that autoimmunity and other immunologic-/inflammatory components play a crucial role in the pathogenesis and in the development of complications such as necrosis. Our research attempts to further elucidate the pathogenesis of this disorder and thereby contribute to the development of novel therapeutic strategies.

Study objective

The primary goal of this study is to identify the presence and possible pathogenic role of auto-antibodies in scleritis patients. Secondary goals are to evaluate the presence and role of matrix metalloproteinases (MMPs) in scleritis and its complications. In addition we attempt to determine specific biomarkers for activity of scleritis or the development of scleritis in systemic disorders as well as its possible HLA associations.

Study design

This multicenter study will take approximately 4 years. The coordinating center is the Erasmus Medical Center. Samples will be collected prospectively at

participating centers.

Study burden and risks

The risks associated with participation in our project can be considered negligible and the burden minimal. Blood and tear fluid samples will be taken during regular ophthalmological evaluation and patients will not be asked to perform any additional activities or suffer from any additional invasive procedures. The results of this study may be beneficial to the subjects by elucidating the pathogenesis of scleritis and revealing possible new targets for therapy. In addition, novel biomarkers of disease activity may improve treatment monitoring.

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

Patients with scleritis with a minimum age of 18 years.

Exclusion criteria

Patients who are younger than 18 years old, who are mentally not competent, or patients with insufficient knowledge of the Dutch language.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-04-2020
Enrollment:	245
Type:	Actual

Ethics review

Approved WMO

Date:	10-03-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	25-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Not approved Date:	06-03-2025
Application type:	Amendment
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	NL71698.078.19