

Pathogenetic insight in idiopathic orbital inflammation

Published: 13-02-2007

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This study aims to gain insights in the pathogenesis of idiopathic orbital inflammation, with ultimately a directer and more effective therapy.

Ethical review	Not approved
Status	Will not start
Health condition type	Eye disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON30470

Source

ToetsingOnline

Brief title

Idiopathic orbital inflammation

Condition

- Eye disorders NEC

Synonym

idiopathic orbital inflammation, orbital inflammation of unknown etiology

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: subsidie is aangevraagd bij de Dr. F.P. Fischer stichting

Intervention

Keyword: idiopathic orbital inflammation, orbital pseudotumor, pathogenesis

Outcome measures

Primary outcome

Prospective case-control study: infectious study: presence/absence of twenty viruses and micro-organisms; genomic study: differential expression of twenty-five proteins involved in inflammation and tissue (re)-generation.

Secondary outcome

none

Study description

Background summary

Idiopathic orbital inflammation is a relatively common disease of the orbit. About half of patients have incomplete responses to current steroid therapy and recurrences are common. Therefore, a better therapy is sought for. The pathogenesis of idiopathic orbital inflammation is still unrevealed.

Study objective

This study aims to gain insights in the pathogenesis of idiopathic orbital inflammation, with ultimately a directer and more effective therapy.

Study design

Three questions are considered:

1. Is there an infectious trigger dysregulating the immune system in idiopathic orbital inflammation?
2. What genetic predisposition and environmental variables are of importance in the pathogenesis of idiopathic orbital inflammation?
3. What pathologic processes are identified to be of importance on a genomic scale?

The study is subdivided in a retrospective case-control study to answer question two and a prospective study with tissue biopsies to answer questions

one and three. The case-control study is not part of this application.

Study burden and risks

Currently in the Netherlands, biopsies are performed in the vast majority of patients in which a diagnosis of idiopathic orbital inflammation is considered. For these patients there is only a small burden of extra administration (10-20 minutes). In about 20% of cases one is more prone to take a biopsy for this study. For those patients the burden is a hospital admittance and an operation under general anesthesia. They profit from a histologic diagnosis and a directer treatment. Vision and motility risks are avoided.

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

Adult patients presenting to the ophthalmology clinic with signs of (sub) acute infiltration and inflammation of intraorbital structures together with symptoms of eyelid edema, conjunctival injection, chemosis, pain and/or motility disturbances.

Exclusion criteria

Exclusion of identifiable local causes such as neoplasia, primary infection and systemic diseases like Wegener and Graves'.

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:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Not approved	
Date:	13-02-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL14931.041.07