Clinical implementation of an uveitis prediction model

Published: 16-05-2018
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To study the effect of the availability of a predictive uveitis model in the clinical setting on the 1 year visual outcome of patients.

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

Summary

ID

NL-OMON46803

Source
ToetsingOnline

Brief title
Uveitis prediction model

Condition

- Ocular infections, irritations and inflammations

Synonym
Uveitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Medication, Prediction model, Uveitis, Visual acuity

Outcome measures

Primary outcome

Best corrected visual acuity.

Secondary outcome

Duration and dose immunosuppressives.

See Ch. 8 of the protocol.

Study description

Background summary

Uveitis is a potentially sight threatening eye disease. There are no clear guidelines or studies directing therapy. Based on cohort studies regarding outcome in subentities of uveitis and clinical experience, therapeutic decisions are made on an ad hoc basis during, and adapted to, the course of the invidual eye*s uveitis. A predictive model has been built and internally validated using cohort and individual disease activity and therapy to predict the resulting visual outcome.

Study objective

To study the effect of the availability of a predictive uveitis model in the clinical setting on the 1 year visual outcome of patients.

Study design

Non-randomised, controlled trial.
Study group 1: historical cohort, group 2: use of the predictive model.

Intervention

Introduction of information of a predictive model.

Study burden and risks

Participants are not subjected to any additional time/burden or risk.

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

- Non-infectious uveitis.
- Age >= 18 years.
- Informed consent.

Exclusion criteria

- Major eye condition preventing any VA improvement or reduction (such as end stage glaucoma, end stage corneal diseases, end stage macular degeneration).
- Suspected or proven infectious uveitis.
- Masquerade syndromes (such as intraocular B cell lymphoma).
- Patients for whom all data of the first year since onset of their uveitis are missing.

- Patients for whom, since onset of their uveitis, data (> 3 years) are missing.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2019
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2018
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	NL63970.078.17