# Clinical implementation of an uveitis prediction model

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Suspended |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON23206

**Source**
Nationaal Trial Register

**Brief title**
Uveitis prediction

**Health condition**

Non-infectious uveitis for at least 3 months.

### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam (OZR)
**Source(s) of monetary or material Support:** ZonMW, Topzorg

### Intervention

### Outcome measures

**Primary outcome**

Change of visual acuity between entry and 12 months.

**Secondary outcome**

- Duration and dosage of immunosuppressive medication.

- Change of inflammatory activity between entry and at 12 months.

- Difference between predicted and achieved VA at 12 months.

- Accuracy of predicted VA.

- Difference between predicted and actual inflammatory activity at 12 months.

- Accuracy of predicted activity.

- Complications.

- VFQ-25.

- Change of outcomes for individual eyes as predicted by the model during the course of the 12 months follow up.

- Change of prediction model perfomance (with respect to legal driving visual acuity, low vision, legal blindness) by means of internal validation.

- IOP.

- OCT.

- The clinician's appraisal of the influence of the predictive model information on the prescribed therapy dosages.

# 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. The objective is 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 objective

It was hypothesized that comparing the course of uveitis of individual eyes with respect to inflammatory activity and visual acuity (VA), and the impact of particular therapies, to already available data about course and outcome from other patients would be of better

predictive value than demonstrated, as yet, by identifying group-specific phenotypic and genotypic risk factors.

### Study design

0 and 12 moths.

### Intervention

Introduction of information of a predictive model.

## Contacts

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## Eligibility criteria

### Inclusion criteria

- Non-infectious uveitis for at least 3 months.

- 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 from a substantial period of time (> 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: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Suspended |
| Start date (anticipated): | 01-06-2018 |
| Enrollment: | 250 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 24-04-2018 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL6983 |
| NTR-old | NTR7172 |
| Other | NL63970.078.17 : OZR-2014-21 |

# Study results