# Detection of perifoveal microvascular changes in Behçet Disease measured with OCT-A

Published: 19-04-2018 Last updated: 17-08-2024

To compare, the perifoveal microvascular changes (non-perfusion areas) in the deep capillary plexus layer between Behçet patients with and without ocular involvement and control subjects, using OCT-A.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational non invasive

# Summary

### ID

NL-OMON46672

**Source** ToetsingOnline

**Brief title** Behçet disease imaged with OCT-A

# Condition

• Retina, choroid and vitreous haemorrhages and vascular disorders

**Synonym** Behcet disease

**Research involving** Human

# **Sponsors and support**

**Primary sponsor:** Oogziekenhuis Rotterdam **Source(s) of monetary or material Support:** Stichting SWOO-Flieringa

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### Intervention

Keyword: Behçet disease, Microvascularisation, Perifoveal, Uveitis

### **Outcome measures**

#### **Primary outcome**

Non-perfusion areas in the deep capillary plexus (DCP).

#### Secondary outcome

Other non-perfusion areas, visual acuity, retinal and choroidal thickness,

macular edema and (subjectively) observed microvascular abnormalities.

# **Study description**

#### **Background summary**

Behçet disease (BD) is a systemic vasculitis, with ocular involvement in up to 70% of the patients. This is most often expressed in bilateral panuveitis with retinal vasculitis. The new non-invasive image modality, optical coherence tomography angiography (OCT-A), was deployed in patients with Behçet Uveitis (BU) in previous studies, showing deviances in non-perfusion areas in the retinal capillary plexus and foveal avascular zone (FAZ) compared to control subjects. It is unknown whether OCT-A images of Behçet patients without ocular involvement show similar subclinical vascular abnormalities.

#### **Study objective**

To compare, the perifoveal microvascular changes (non-perfusion areas) in the deep capillary plexus layer between Behçet patients with and without ocular involvement and control subjects, using OCT-A.

#### Study design

Case-control study.

#### Study burden and risks

The study measurements involve best corrected visual acuity (BCVA), fundus photography, OCT macular volume scans and OCT-A plots. All non-uveitis subjects

will also undergo a full ophthalmic evaluation. The burden is considered low, the diagnostic tests are non-invasive and not time-consuming. The total duration is estimated to be 3 hours. There will be an effect due to the mydriatic drop, used for pupil dilation, which will last for 2-4 hours after the examinations.

# Contacts

**Public** Oogziekenhuis Rotterdam

Schiedamse Vest 180 Rotterdam 3011 BH NL **Scientific** Oogziekenhuis Rotterdam

Schiedamse Vest 180 Rotterdam 3011 BH NL

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

# **Inclusion criteria**

All participants: Signed informed consent At least 18 years old;Behcet & Uveitis patients: Diagnosed with Behçet disease, at least 1 year ago Diagnosed with Behçet uveitis at least 6 months ago;Behcet patients without Uveitis:

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Diagnosed with Behçet disease, at least 1 years ago Not diagnosed with Behçet uveitis;Healthy volunteers: No known chorioretinal pathologies or uveitis

# **Exclusion criteria**

Ocular surgery within the last 3 months, except for uncomplicated cataract surgery Participation in another ophthalmic trial using an investigational drug within the last 12 weeks

Other active ocular diseases which irreversibly compromise visual acuity or good visualization of the study eye

# Study design

# Design

Observational non invasive
Other
Non-randomized controlled trial
Open (masking not used)
Active
Diagnostic

### Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2018
Enrollment:	90
Туре:	Actual

# **Ethics review**

Approved WMODate:19-04-2018Application type:First submission

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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 CCMO **ID** NL64694.078.18