# Multifocal electroretinogram abnormalities in inflammatory cystoid macular edema.

Published: 08-08-2017 Last updated: 10-08-2024

To investigate to which extent macular function is affected in patients with inflammatory CME as measured by mfERG.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders
Study type	Observational non invasive

# **Summary**

#### ID

NL-OMON47097

**Source** ToetsingOnline

Brief title mfERG CME

### Condition

• Eye disorders

**Synonym** cystoid macular edema, uveitis

**Research involving** Human

#### **Sponsors and support**

#### Primary sponsor: UMC Utrecht

**Source(s) of monetary or material Support:** Vereniging Bartimeus Sonneheerdt; Dr. F.P. Fischerstichting

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#### Intervention

Keyword: CME, mfERG, uveitis

#### **Outcome measures**

#### **Primary outcome**

To investigate to which extent macular function is affected in patients with inflammatory CME as measured by mfERG. Multifocal ERGs will be analyzed on amplitude, implicit time, and waveform.

#### Secondary outcome

- 1. To which extent mfERG abnormalities are reversible after treatment.
- 2. To which extent clinical parameters, including demographics, treatment and

ophthalmologic examination results (e.g. OCT value, visual acuity, severity of

inflammation scored according to SUN) influence and/or correlate to mfERG

abnormalities.

3. To which extend the 30HZ flicker response can be correlated to the mfERG

and clinical parameters.

# **Study description**

#### **Background summary**

Uveitis is a major cause of severe visual impairment. It is often chronic and is treatable with steroids, biologicals and disease-modifying antirheumatic drugs (DMARDs). However, a series of severe complications can occur. Cystoid macula edema (CME) is a frequent complication of uveitis and the main cause of blindness and vision loss. CME is treatable, after which usually vision improves. However, in some patients vision does not improve after CME treatment. Complications of treatment of CME include cataracts and an increase of intraocular pressure. Multifocal electroretinogram(mfERG) is a diagnostic method for analysis of different regions of the retina, including the macula. Multifocal ERG can therefore be used to determine macular function in relation to (chronic) CME. mfERG can therefore give insights in CME.

#### **Study objective**

To investigate to which extent macular function is affected in patients with inflammatory CME as measured by mfERG.

#### Study design

Pilot study

#### Study burden and risks

The performance of a mfERG takes approxamately 30-45 minutes, a 30Hz flicker respons approx. 1 minute.. Patients will have 2 mfERGs and 30Hz flicker responses. These are non-painfull, non-invasive tests. The risks associated with a mfERG and 30Hz flicker response are negligible. Disposable DTLs are used. Eye droplets that are administerd have been administered multiple times to these patients at routine ophthalmologic visits.

## Contacts

**Public** UMC Utrecht

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# **Trial sites**

#### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

#### **Inclusion criteria**

- Age \*18 years

- Inflammatory CME requiring (different) treatment
- Mentally competent

### **Exclusion criteria**

- Age <18 years
- Patients diagnosed with diabetes, a retinal occlusion or other causes of CME.
- Patients with a history of treatment with medication that alter macular function i.e. hydroxychloroquine, tamoxifen.
- Patients with severe puckering
- Patients diagnosed with conditions other than uveitis, that can influence macular function
- i.e. age related macular degeneration, Stargardt etc.
- Patients with a severe vitreous haze or severe cataracts

# Study design

### Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

#### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2017
Enrollment:	40

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Type:

Actual

### Medical products/devices used

Generic name:	multifocal electroretinogram
Registration:	Yes - CE intended use

# **Ethics review**

Approved WMO	
Date:	08-08-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	29-08-2018
Application type:	Amendment
Review commission:	METC NedMec

# **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** NL58823.041.17