Photoreceptor damage in uveitis measured by ElectroRetinoGram

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To objectively investigate retinal function deterioration due to the inflammatory process by ERG. To investigate if risk factors for loss of ERG activity in uveitis herald more aggressive immunomodulation treatment to prevent visual loss.

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

Summary

ID

NL-OMON42971

Source
ToetsingOnline

Brief title
ERG Uveitis

Condition

- Eye disorders
- Autoimmune disorders
- Hepatobiliary neoplasms malignant and unspecified

Synonym
anterior and/or intermediate and/or posterior uveitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Vereniging Bartimeus Sonneheerdt;Dr.F.P.Fischerstichting

Intervention

Keyword: electroretinogram, prognostic, uveitis

Outcome measures

Primary outcome

The retinal function measured by ERG is the main outcome of the study. ERG reduction, reflecting retinal damage, will be analysed throughout the course of uveitis. ERGs will be evaluated on several parameters, including a and b wave amplitude, latency, waveform, b:a wave ratio, and oscillatory potentials.

Secondary outcome

- When ERG reduction, reflecting retinal damage, occurs in the course of uveitis.

- To which extent different forms of uveitis, i.e. anterior, intermediate, posterior, panuveitis or specific diagnosis influence ERG abnormalities

- To which extent clinical parameters, including demographics, treatment and ophthalmologic examination results (e.g. visual acuity, severity of inflammation scored according to the SUN criteria18, flare, presence of CME, retinal vasculitis or chorioiditis on FA, OCT values and visual fields) influence ERG abnormalities.

- To which extent ERG abnormalities are reversible.

Study description

Background summary

Uveitis is a major cause of severe visual impairment. It is often of a chronic nature and is treatable with steroids and other immudolatory drugs. However, a

series of severe complications can occur. Several studies have objectivized the retinal damage which can occur due to ocular inflammation in certain forms of uveitis by measuring full field electroretinogram (ffERG). If electroretinogram (ERG) changes can predict early subclinical tissue damage, it is a helpful tool to monitor patients for the treatment of uveitis. Since ERG abnormalities in uveitis might be irreversible, deterioration of ERG might indicate more aggressive treatment strategies with immunomodulating agents early in the disease process. Furthermore, knowledge about functional aspects of the retina measured by ERG in uveitis, can give insight in the pathogenesis of tissue damage in the course of the disease.

Study objective

To objectively investigate retinal function deterioration due to the inflammatory process by ERG. To investigate if risk factors for loss of ERG activity in uveitis herald more aggressive immunomodulation treatment to prevent visual loss.

Study design

Observational, cohort study.

Study burden and risks

The performance of an ERG takes up to 30 minutes to an hour. It is a non-painful, non-invasive test. The risks associated with an ERG are negligible.

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

Age *18 years
Diagnosed with uveitis
Mentally competent

Exclusion criteria

Patients who do not speak or understand the Dutch language will be excluded from participation in this study.
Age *18 years
Patients with a family history of retinal dystrophy.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-06-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-10-2016
Application type:	Amendment
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	NL56732.041.16