# Normative values of ERGs, and association between photoelectric response and retinal thickness as a function of age: The Erasmus ERG Study

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This study has the following goals: 1. Generation of normative values for full-field ERGs within single recording sessions according to ISCEV standard.2. To compare function (results of full-field ERG) with anatomy (retinal thickness on OCT) in...

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

# Summary

### ID

NL-OMON34672

**Source** ToetsingOnline

Brief title The Erasmus ERG Study

## Condition

• Retina, choroid and vitreous haemorrhages and vascular disorders

#### Synonym

niet van toepassing> onderzoek bij gezonde personen

#### **Research involving**

Human

### **Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

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### Source(s) of monetary or material Support: Henkes Stichting

### Intervention

**Keyword:** full-field electroretinography (ERG), normative values, optical coherence tomography (OCT), retina

### **Outcome measures**

#### **Primary outcome**

Determinants: age, sex

Outcomes:

ERG: amplitudes and implicit times

OCT: retinal thickness

### Secondary outcome

niet van toepassing

# **Study description**

#### **Background summary**

The International Society for Clinical Electrophysiology of Vision (ISCEV) demands that each laboratory which records ERGs establishes normative values for its own equipment and patient population. Age and sex are factors known to influence ERG outcomes.

Optical Coherence Tomography (OCT) is an imaging technique in which high-resolution images of ocular structures are generated and is particularly useful in the diagnosis and management of retinal disorders. The relation between function and anatomy of the retina in healthy subjects is currently unclear.

#### Study objective

This study has the following goals:

1. Generation of normative values for full-field ERGs within single recording sessions according to ISCEV standard.

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2. To compare function (results of full-field ERG) with anatomy (retinal thickness on OCT) in normal subjects.

### Study design

The design is a cross-sectional observational study in which we will perform full-field ERGs and OCT scans on healthy persons to establish normative values for our laboratory. Participants will be invited for a one-time ophthalmological examination, full-field ERG recording and an OCT scan. The duration of these examinations is approximately two hours per participant; the entire data collection will take place during one year.

#### Study burden and risks

The ophthalmologic tests, ERG exam and OCT are non-invasive standard procedures at our hospital. The pupil dilation with Phenylephrine HCL 2,5% ocgtt and Tropicamide 0,5% ocgtt is necessary to record an accurate ERG and OCT scan. Side effects of these drops include photophobia and reduced accommodative power during 2 hours. There is a very low risk of acute angle-closure glaucoma; 3:10.000 (Wolfs RCW et al; IOVS 1997). If this occurs, we will examine and treat the patient according to standard care at Dept. Opthalmology at Erasmus MC.

# Contacts

**Public** Erasmus MC, Universitair Medisch Centrum Rotterdam

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Children (2-11 years) Elderly (65 years and older)

### **Inclusion criteria**

subjects with a visual acuity >= 0.7, refractive error between +3D and -3D no history of retinal, neurological or systemic disorders, no known family history of heritable retinal disease

### **Exclusion criteria**

subjects with a visual acuity <0.7 refractive error not between +3D and -3D history of retinal, neurological or systemic disorders family history of heritable retinal disease

# Study design

### Design

Study type: Observational non invasive<br/>Masking:Open (masking not used)Control:UncontrolledPrimary purpose:Basic science

### Recruitment

NL

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Recruitment status:	Recruiting
Start date (anticipated):	26-07-2010
Enrollment:	50
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	08-07-2010
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** CCMO ID NL31882.078.10