ISRCTN09017572 https://doi.org/10.1186/ISRCTN09017572

Normal values for central retinal thickness asymmetry in healthy Caucasians

Submission date
27/02/2014

Recruitment status
No longer recruiting

Registration date
27/03/2014

Overall study status
Completed

Last Edited
16/06/2015

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Glaucoma is a term that describes a group of eye conditions that affect vision. Several previous studies in glaucoma patients have shown the importance of structural changes in the retina, a complex layer of tissue at the back of your eye. Optical coherence tomography (OCT) is a technique which uses a light beam to scan the different layers of the retina and can detect very subtle changes. A new OCT software assesses any possible asymmetry between the two eyes and the upper and lower hemisphere in both eyes. Recent studies have found that retinal asymmetry may be the first sign in the development of glaucoma. However, at present we have no information regarding the 'normal' asymmetry values in healthy individuals, therefore it is hard to distinguish 'normal' asymmetry from asymmetries which may be early signs of glaucoma. Our aim is to study the retinal asymmetry that normally exists in healthy individuals.

Who can participate?
Healthy volunteers between the ages of 18 and 45 who have no eye disease and have normal visual acuity with no or minor correction (glasses or contact lenses).

What does the study involve?
Every volunteer will undergo a general eye examination (visual acuity and slit lamp examination) and an OCT scan.

What are the possible benefits and risks of participating?
Volunteers participating in our study may have the benefit of a detailed eye examination. The study has no extra risk in comparison to a general eye examination.

Where is the study run from?
Our study will run at the Department of Ophthalmology, Thy-Mors Hospital in Thisted, Denmark.

When is the study starting and how long is it expected to run for?
The study will run from March 2014 to July 2014.

Who is funding the study?
Department of Ophthalmology, Thy-Mors Hospital, Denmark.

Who is the main contact?
Janos Hargitai
janos.hargitai@rn.dk

Contact information

Type(s)
Scientific

Contact name
Dr Janos Hargitai

Contact details
Højtoftevej 2
Thisted
Denmark
7700
-
janos.hargitai@rn.dk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Normal values for central retinal thickness asymmetry in healthy Caucasians, measured by Spectral-Domain optical coherence tomography (OCT) posterior pole asymmetry analysis

Study objectives
To determine the normal variation in central retinal thickness asymmetry in healthy Caucasians using Spectralis HRA+OCT's posterior pole asymmetry analysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee of North Jutland (Den Videnskabsetiske Komité for Region Nordjylland), 24/01/2014

Study design

Cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Retina

Interventions
1. Visual acuity measured using the Snellen Chart
2. Retinal thickness and RNFL measured by Spectralis HRA+OCT's volume and circle scan mode, respectively

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Right eye - left eye retinal thickness asymmetry of the paired 64 cells in the posterior pole retina thickness map
2. Superior-inferior retinal thickness asymmetry of the paired 32 cells

Outcome measures will be assessed at baseline.

Secondary outcome measures
1. Variance in asymmetry across the macula
2. Association between the temporal RNFL thickness and the mean central retinal thickness
3. Effect of age and sex on interocular asymmetry
Outcome measures will be assessed at baseline.

Overall study start date
01/03/2014

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Healthy volunteer
2. Caucasian
3. Age 18-45 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Visual acuity < 1.0
2. Spherical equivalent > 1.5 D
3. Morphological changes in macula
4. Retinal nerve fiber layer (RNFL) thickness out of normal limits

Date of first enrolment
01/03/2014

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
Denmark

Study participating centre
Højtoftevej 2
Thisted
Denmark
7700

Sponsor information

Organisation
Thy-Mors Hospital (Denmark)

Sponsor details
Højtoftevej 2
Thisted
Denmark
7700
-
janos.hargitai@rn.dk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Thy-Mors Hospital (Denmark)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No