Natural Peripheral Vision

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Development of a method and diagnostic instrumentation for characterizing the peripheral ocular characteristics of normal subjects (with healthy eyes) in a clinical setting.Primary objective of the study: To measure the distribution of the ocular...

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

Summary

ID

NL-OMON45078

Source
ToetsingOnline

Brief title
NPV

Condition

- Eye disorders NEC

Synonym
Cataract, staar

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: AMO,Eureka subsidie

Intervention

Keyword: Cataract, Intraocular lens, MRI

Outcome measures

Primary outcome

1. Ocular geometry measurement using MRI imaging and ocular biometry

The main study parameters are the 3D-shape of the eye and the distances and curvature between the front and back cornea, the front and back of the crystalline lens, the equator of the eye, the retina and the sclera. From these parameters we will derive the variation between those parameters within the group and correlate them to the results from the current ophthalmology measures.

Secondary outcome

2. Clinical method to evaluate natural peripheral vision in patients.

The main study parameters are visual acuity, refraction, central and peripheral wavefront measurements.

Study description

Background summary

Cataract is the leading cause of blindness worldwide (39%, World Health Organization, 2010). Every year over 15 million people worldwide have cataract surgery performed. When a patient undergoes cataract surgery, the cataractous lens is removed and replaced with a prosthetic lens known as an intraocular lens (IOL). Current technology IOLs restore central vision adequately, however, it has been discovered recently that the image quality in the peripheral field of view is significantly reduced by current IOLs. This has potential implications for everyday tasks, such as walking, car driving and manoeuvring in low light conditions. Improving peripheral vision obtained with IOLs may increase postoperative quality of life.

Study objective

Development of a method and diagnostic instrumentation for characterizing the peripheral ocular characteristics of normal subjects (with healthy eyes) in a clinical setting.

Primary objective of the study:
To measure the distribution of the ocular geometry of eyes of the healthy population using MRI imaging and ocular biometry. Investigate the variance in the eye shape of young and old subjects.
Next to this, we will verify wether the ocular geometrie is changed by the insertion of an intraocular lens.

Secondary objective of the study:
To establish a clinical method to evaluate natural peripheral vision in patients.

Study design

The study is a single center quantitative cross-sectional study to measure the natural geometry and peripheral ocular characteristics of the eye. The study will consists of a group of 90 subjects.
The subjects will undergo a MRI scan protocol at the 7 Tesla Philips scanner followed by an extensive ophthalmic evaluation. The cataract patients will furthermore receive an additional MRI scan protocol prior to the cataract surgery.

Study burden and risks

The risks of this study are the standard risks related to MRI. These risks will be minimized by screening the subjects through a questionnaire for MRI safety via telephone two weeks before the study day and prior to the examination. The questionnaire will cover the risk factors associated with MRI. Based on the answers, the subject will be allowed or not allowed to go into the scanner.

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

subjects with virgin eyes or patients undergoing cataract surgery

Exclusion criteria

Healthy volunteers:
ocular pathology
prior intra- or extraocular surgery
contra-dindication to MRI scanning;Cataract patients:
ocular pathology other than cataract
prior intra- or extraocular surgery
contra-dindication to MRI scanning

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2013
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	23-01-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	13-07-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL45166.058.13

Study results

Date completed: 01-01-2018

Actual enrolment: 47

Summary results
Trial is onging in other countries