Virtual Refractive Surgery for the Prevention of Negative Dysphotopsia

Published: 12-09-2016
Last updated: 15-04-2024

Primary objective: - Uncovering the underlying optical origin of ND.Secondary objectives:- Determining the key aspects of IOL design to prevent ND- Develop a Virtual Refractive Surgery application for the prevention and treatment of ND.

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

Summary

ID

NL-OMON47193

Source
ToetsingOnline

Brief title
vRESPOND

Condition

- Vision disorders

Synonym
Negative dysphotopsia; Shadows in the visual field

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: European Society of Cataract and Refractive Surgeons

Intervention

Keyword: Intraocular lens, Negative Dysphotopsia, Raytracing, Refraction surgery

Outcome measures

Primary outcome

The measured and ray-traced peripheral aberrations and their relation to the symptoms described in the questionnaires.

Secondary outcome

- A description of the effect of different IOL designs on negative dysphotopsia.

- Description of the progression/regression of negative dysphotopsia in the first year after cataract surgery.

- The assessment of the potential clinical value of static perimetry to quantify the visual field loss in ND.

- The assessment of the performance of the eye models for unusual eyes.

Study description

Background summary

Negative Dysphotopsia (ND) is a complication that presents itself after an otherwise uncomplicated cataract surgery. During cataract surgery the original crystalline lens, which has become clouded, is extracted and replaced by an artificial *intraocular* lens (IOL). ND is manifested as a persistent dark shadow in the patients* visual field. Due to the lack of knowledge on the origin of ND, no effective method to prevent or treat this condition is currently available. This study aims to fill this gap through the optical simulations using patient-specific models of the eye, based on MRI and corneal topography data. With these eye-models we aim to uncover the cause of ND and subsequently assess the efficacy of different treatment options through ray-tracing simulations.

Study objective

Primary objective:
- Uncovering the underlying optical origin of ND.

Secondary objectives:
- Determining the key aspects of IOL design to prevent ND
- Develop a Virtual Refractive Surgery application for the prevention and treatment of ND.

Study design

A single center, causal research, non-blinded, prospective study.

Study burden and risks

The study evaluation consists of an extensive ophthalmic evaluation complemented by an ocular-MRI scan and two short questionnaires. The amount of evaluation points differs for each study group:
- The subjects without ND: 1 evaluation
- The subjects with recently developed ND (<3 months): 3 evaluations
- The subjects with persistent ND (>3 months), who are scheduled for an IOL exchange or an piggyback IOL implantation as a part of their treatment: 2 evaluations
- The subjects with persistent ND (>3 months) who have already had unsuccessful treatment before: 1 evaluation
- The subjects with abnormally shaped eyes or very high refractive errors: 1 evaluation.

The risks associated with participation are the potential risks involved with the high magnetic fields present around an MRI scanner. As all subjects will be screened for potential contra-indication for MR-scanning, all potential risks of this study are effectively removed.

There will be no direct benefit for the subjects in this study. However, it will contribute to the knowledge of ND, which might benefit the patients with ND in the future.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA

NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age *18 years
2. Gender: both male and female
3. Uncomplicated cataract surgery
4. For the groups with ND: complaints of negative dysphotopsia following cataract surgery
5. For the group without ND: no complaints of negative dysphotopsia following cataract surgery

Exclusion criteria

1. Age <18 years;2. Prior refractive surgery, for instance:
a. Phakic IOL implantation
b. Laser eye surgery, including:
I. LASEK
II. LASIK
III. PRK;3. Conditions limiting the visual field, for instance:
a. Glaucoma
b. Retinal ablation;4. Conditions limiting the visual acuity which are expected to hinder an accurate ray-tracing analysis by the physician or investigators, for instance corneal diseases.;5. Contraindications to MRI scanning, including:

a. Claustrophobia
b. Pregnancy
c. Pacemakers and defibrillators
d. Nerve stimulators
e. Intracranial clips
f. Metallic fragments
g. Cochlear implants
h. Ferromagnetic implants
i. Hydrocephalus pump
j. Permanent make-up
k. Tattoos above the shoulders
l. Piercings (unless they can be taken out)
m. Subjects who cannot keep their head still (eg. Tremor, Parkinson*s disease)
n. Severe physical restriction (completely wheelchair dependent);In the case of uncertainty about the MRI-contraindications, the MR-safety commission of the radiology department will decide whether this subject can be included in the study or not.

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):	14-11-2016
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO

Date:	12-09-2016
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	04-04-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	06-10-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL58358.058.16

Study results

Date completed:	31-08-2020
Actual enrolment:	66