Molecular background of endothelial cell loss in patients with phakic intraocular lenses (MoBack-ECL): a tear and aqueous humour analysis study

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Ethical review	Approved WMO
Status	Completed
Health condition type	Anterior eye structural change, deposit and degeneration
Study type	Observational non invasive

Summary

ID

NL-OMON56417

Source
ToetsingOnline

Brief title
MoBack-ECL: a tear and aqueous humour study

Condition

- Anterior eye structural change, deposit and degeneration

Synonym
Endothelial cell loss, sub-clinical inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W,Landelijks stichting voor Blinden en Slechtzienden;en algemene Nederlandse vereniging ter voorkoming van blindheid.

Intervention

Keyword: Aqueous humour, Biomarkers, phakic intraocular lense, Tears

Outcome measures

Primary outcome

The main study parameter is difference in pro-inflammatory cytokine levels - among others MMP9- between patients undergoing a pIOL explantation in combination with a cataract surgery compared to pro-inflammatory cytokine levels of patients only undergoing cataract surgery in aqueous humour.

Secondary outcome

The secondary parameter is the correlation between cytokines in aqueous humour and their expression in tears.

Study description

Background summary

The number of highly myopic patients is increasing. Especially in East and Southeast Asia, up to 90% of adolescents are currently myopic. Long-term treatment of high myopia can be obtained by three types of surgery: laser refractive surgery, phakic intraocular lens (pIOL) implantation, and refractive lens exchange Implantation with a pIOL is the preferred treatment for high myopes, resulting in increasing patient numbers implanted due to the increasing numbers of patients with high myopia.
Long-term results show that implantation of a pIOL induces an accelerated decrease in corneal endothelial cells (EC). Although some risk factors for increase EC loss have been identified, the underlying mechanism is currently unknown. It is hypothesized that the aqueous flow in the anterior segment of the eye (i.e. anterior chamber) is disturbed, causing an altered nutritional flow in the anterior chamber. Another hypothesis is that the pIOL causes chronic subclinical inflammation in the anterior chamber resulting in increased

EC loss. Currently there is insufficient proof to confirm or reject either hypothesis. If one of these hypotheses can be confirmed, it is likely to induces significant changes in clinical practice.

Study objective

The primary objective of the study is to explore the role of inflammation in the anterior chamber on endothelial cell loss in patients implanted with iris-fixated pIOLs. The secondary objective is to identify whether there is a correlation between biomarkers in aqueous humour and biomarkers in tears, both related to the accelerated progression of EC loss.

Study design

Two strategies are incorporated in the design of this study. The first part will retrospectively evaluate EC loss in patients with iris-fixated (IF) phakic intraocular lenses (pIOLs). The second part is prospective and will compare EC measurements, cytokines in aqueous humour and in tears from patients scheduled for IF-pIOLs explantation and compare them to patients with routine cataract surgery.

Study burden and risks

In both groups preoperatively, tears will be collected using a Schirmer strip. Schirmer strips are small paper strips which are placed behind the lower eyelid, in the inferior fornix of the eye to absorb tear fluid. Tear collection is non-invasive without risk for complications. During surgery, aqueous humour, the phakic intraocular lens, and the lens capsule, will be collected, which will not increase the burden for the patient, nor the risk of an infection.

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 over 18 ,
Cataract in one or both eyes, or indication for phakic intra-ocular lens explantation (Artisan or Artiflex lenses)
Informed and having given informed consent.

Exclusion criteria

• Insufficient understanding of the Dutch language to comply with study procedures
• Inability to complete follow-up or comply with study procedures
• Non-routine cataract surgery (e.g., cataract surgery combined with another ocular procedure - other than pIOL explantation -, cataract surgery under general anaesthe-sia)
• Cognitive or behavioral conditions that might interfere with surgery
• Patients with ocular comorbidities such as: diabetes with vision threatening diabetic retinopathy or diabetic macular edema, glaucoma (or IOP >24 mmHg), keratitis, keratoconus, keratopathy, corneal dystrophy, and uveitis.
• Women who are pregnant or nursing their child
• Immune-compromised patients (e.g., systemic corticosteroid use, leukaemia)
• Factors that increase the risk of complicated surgery:
o Previous ocular surgery (for the control group)
o Previous perforating or blunt eye trauma
o Eye, adnexal, or anatomical abnormalities (including pseudoexfoliation syn-drome)
o Lens luxation or iridodonesis
o Cataract nigrans, posterior polar cataract

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-07-2020
Enrollment:	126
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-09-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL70342.068.19