

Cataract surgery with FED

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In vivo confocal microscopy (IVCM) backscatter measurements is a useful measurement to decide whether patients with FED and cataract should undergo either a phaco or a triple procedure.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28829

Bron

Nationaal Trial Register

Verkorte titel

NA

Aandoening

- Fuchs' endothelial dystrophy
- Cataract

Ondersteuning

Primaire sponsor: The Rotterdam Eye Hospital

Overige ondersteuning: ZonMW, TopZorg

Postbus 93245

2509 AE Den Haag

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

At one month: the number of patients (not) requiring posterior lamellar keratoplasty (PLK);

this in relation to the preoperatively measured corneal backscatter (on in vivo confocal microscope).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Fuchs' endothelial dystrophy (FED) is associated with a reduction of the corneal endothelial cell density (ECD). As cataract surgery may enhance cell loss, and lead to corneal edema and reduced vision, it may become necessary to restore vision by posterior lamellar keratoplasty (PLK). With advanced FED, the ECD itself happens to be an unreliable parameter. Instead, we will evaluate backscatter on in vivo confocal microscopy (IVCM) as a possible decisive preoperative measure for the clinical choice between phaco-emulsification or triple procedure in eyes with FED and cataract.

Objective: To study IVCM backscatter measurements as a usefull measurement to decide between surgical indications.

Study design: Prospective observational trial.

Study population: Patients with advanced FED indicated for cataract surgery.

Intervention: None.

Main study parameters/endpoints: Preoperative corneal backscatter; postoperative number of patients requiring PLK (y/n).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants do not benefit. Assessments will be scheduled at the time of regular visits. Additional measurements include two IVCM assessments which involve contact with the cornea. Extra measurements will take about two times one hour.

Doel van het onderzoek

In vivo confocal microscopy (IVCM) backscatter measurements is a usefull measurement to decide whether patients with FED and cataract should undergo either a phaco or a triple procedure.

Onderzoeksopzet

Preop, 1 month.

Onderzoeksproduct en/of interventie

None.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age $\geq$ 18 years.
- Informed consent.
- FED stage $\geq$ 2.
- Cataract requiring surgery.
- Visual acuity (VA) $<$ 0.5.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Indication for triple procedure.
- History of other ocular disorders affecting VA.
- History of intra-ocular, corneal or refractive surgery.
- Severe nystagmus.
- Corneal opacity in the pre-pupillary region not related to FED.
- Corneal neovascularization > 1 quadrant.
- Amblyopia.
- Expected VA after surgery < 0.6.
- Fellow eye already included in this study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	03-06-2015
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum: 02-06-2015

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42593

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5067
NTR-old	NTR5198
CCMO	NL52626.078.15
OMON	NL-OMON42593

Resultaten

Samenvatting resultaten

Engel A, Wubbels R, van Goor T, Remeijer L, Geerards AJ, Vigueras-Guillén JP, van Rooij J. Pre-operative measurements to decide whether to combine a cataract surgery and a keratoplasty in eyes with Fuchs' endothelial dystrophy, Acta Ophthalmol. 97 (Suppl. S262), 5-6, 2019. [Abstract]