Prospective, Feasibility study to evaluate the safety of the EndoArt* for Treatment of Subjects Suffering from Corneal Edema

Published: 24-07-2017
Last updated: 15-04-2024

To evaluate the safety of the EndoArt* implanted in subjects suffering from corneal edema.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders
Study type	Interventional

Summary

ID

NL-OMON53003

Source
ToetsingOnline

Brief title
Safety of the EndoArt* for Treatment of Corneal Edema

Condition

- Eye disorders

Synonym
'Corneal edema', 'Corneal swelling'

Research involving
Human

Sponsors and support

Primary sponsor: EyeYon Medical
Source(s) of monetary or material Support: EyeYon Medical

Intervention

Keyword: Cornea, Edema, Implant

Outcome measures

Primary outcome

The frequency and severity of all treatment-related adverse events, during and after implantation of the EndoArt* and throughout the 6 month follow-up period. Adverse events will be assessed on a continuous basis from the procedure through the study completion at 6 months. Related adverse events include: corneal perforation, melting, uncontrolled inflammation, severe infection.

Secondary outcome

* Corneal thickness

* Subjective corneal clarity

* Pain as assessed by a Visual Analogue Scale (VAS)

* Measurement Best Corrected Distance Visual Acuity (BCDVA)

Study description

Background summary

The posterior corneal surface is lined by the corneal endothelium, which maintains corneal clarity. The endothelial cell layer functions passively as a barrier to the influx of aqueous into the stroma and functions actively by pumping excess fluid out of the stroma via pumps. Endothelial cell density decreases at a rate of ~0.5% year; when endothelial cell density decreases to a critical threshold, the cornea swells and eventually decompensates into bullous keratopathy.
The EndoArt* device will serve as a water impermeable barrier and provide a physical barrier to the passive movement of aqueous humor into the corneal stroma. With the effect of evaporation from the corneal surface, it may maintain corneal dehydration and clarity. The lack of endothelial pump in the silicon layer may be compensated by the decreased permeability of the silicon

relative to the natural endothelium.

Study objective

To evaluate the safety of the EndoArt* implanted in subjects suffering from corneal edema.

Study design

Prospective interventional study with 20 participants.

Intervention

EndoArt* implantation behind the cornea with or without endothelium removal.

Study burden and risks

Risks that may be associated with implantation of the EndoArt* are similar in nature to those encountered with other Endothelial keratoplasty e.g. DSEK (Descemet stripping endothelial keratoplasty) or DMEK (Descemet membrane endothelial keratoplasty).
The following are possible risks the subject may experience from participation in this research:
* Anterior or posterior synchiea
* Cornea abrasion, opacity
* Device Detachment and further surgical manipulation
* Worsening of corneal edema
* Cornea thinning and perforation
* IOP elevation due to procedure or steroids
* Infection
* Inflammation
* Cataract induction
* Retinal detachment

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subject is over 40 years old
2. Subject with chronic corneal edema.
3. Subject with corneal thickness >650 µm
4. Subject with visual acuity 6/30 or worse (equivalent ETDRS).
5. Subject with better visual acuity in the contralateral eye.
6. Pseudophakic subject (anterior or posterior) with stable IOL.
7. Subject understands the study requirements and the treatment procedures and provides written Informed Consent before any study-specific tests or procedures are performed.

Exclusion criteria

1. Subject with best corrected visual acuity of 6/30 or worse in the fellow eye
2. Subject with history of ocular Herpes keratitis
3. Subject with severely scarred cornea (unfit for regular endothelial keratoplasty)
4. Subject with irregular posterior cornea (e.g. post PKP)
5. Subject who is suffering from infection of the cornea
6. Patients with band keratopathy and/or limbal stem cell deficiency.
7. Subject with clinical moderate to severe dry eye
8. Subject with phthisis or phthisis suspect
9. Subject with low ocular pressure *6 mmHg or higher than 25 mmHg.
10. Subject with aphakica

11. Subject with pseudophakodonesis
12. Subject with large iris defect which can compromise intraoperative AC stability.
13. Subjects after corneal refractive surgery.
14. Subject with glaucoma shunt (e.g. Ahmend valve)
15. Subject with neurotrophic corneal history
16. Subject with history of persistent corneal erosion difficulties with epithelial growth (re-epithelization)
17. Subject who is currently participating or have participated in an investigational study, other than this study, within the past 60 days

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2019
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	Endothelial keratoprosthesis
Registration:	No

Ethics review

Approved WMO

Date:	24-07-2017
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2021
Application type:	Amendment

Review commission: METC Amsterdam UMC

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	NL59331.018.16