Prospective, open label, single arm, First in Human (FIH) clinical study to assess Safety and efficacy of the CorNeat Keratoprosthesis for the treatment of corneal blindness

Published: 15-10-2021
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The objective of this clinical study is to prove the safety of the CorNeat KPro.

Ethical review	Approved WMO
Status	Pending
Health condition type	Anterior eye structural change, deposit and degeneration
Study type	Interventional

Summary

ID

NL-OMON51085

Source
ToetsingOnline

Brief title
Safety assessment of the CorNeat KPro in blind patients

Condition

- Anterior eye structural change, deposit and degeneration

Synonym
Corneal Blindness, Corneal scarring

Research involving
Human

Sponsors and support

Primary sponsor: Corneat Vision Ltd.

Source(s) of monetary or material Support: industry;The sponsor Corneat vision

Intervention

Keyword: biomimetics, Cornea, Corneal Blindness, Corneal Transplantation, Keratoprosthesis, KPro, Synthetic biology

Outcome measures

Primary outcome

Primary Safety Endpoint is the frequency and severity of all unanticipated

adverse device-related events (UADE) or treatment-related adverse events,

during and after implantation of the CorNeat KPro and up to 24 months. The

frequency should be less than SOC (as detailed in the Investigator*s Brochure).

Secondary outcome

Effectiveness Endpoints:

(i) Primary Endpoint: Retention of implant;

(ii) Secondary Endpoint: Improved visual acuity

Study description

Background summary

Corneal pathology is a leading cause of blindness worldwide with 20-30 million patients in need of a remedy and around 2 million new cases/year. The epidemiology of corneal blindness is complex and encompasses injury and a wide variety of infectious, genetic, and inflammatory eye diseases, which cause corneal scarring or opacity and lead to functional blindness.
Current solutions for corneal blindness and disease include penetrating keratoplasty (PKP; corneal transplantation), lamellar keratoplasty (DMEK, DALK), and rarely keratoprosthesis (KPro; artificial cornea implantation). Together, keratoplasty and to a much lesser extent KPros address 5%-10% of global cases due to lack of tissue availability, low graft survival rates and the fact that some corneal blindness indications are not suitable for keratoplasty. Thus, there is an ever-growing number of patients for whom there is no suitable solution.

An artificial solution would solve many shortcomings of the current available treatments and therefore alleviate the suffering of scores of affected individuals, predominantly in the developing world.
So far, attempts at creating scalable KPros have failed. Whereas previous KPros have integrated an artificial lens into a biological substrate that was then implanted into the eye, the CorNeat KPro is entirely synthetic, comprised of a microporous skirt that leverages the subconjunctival space for integration.

Study objective

The objective of this clinical study is to prove the safety of the CorNeat KPro.

Study design

Prospective, open label, single arm, First-in-human (FIH) clinical study to assess safety and efficacy of the CorNeat KPro for the treatment of corneal blindness. Subjects will be followed up for 24 mon

Intervention

The CorNeat KPro will be implanted into the subject*s eye with the optic component snapping into the patient*s trephined cornea then sutured to the eye wall using 3 non-degradable sutures and the skirt component will be placed under the conjunctiva that will be repositioned to cover the skirt.

Study burden and risks

Taking part in this study poses some known risks such as glaucoma, Retro Prosthetic Membrane (RPM), endophthalmitis, inflammatory reaction around the implant, foreign body sensation, stromal melting, poor post-operative visual quality, intra ocular bleeding, retinal detachment, droopy eyelid.
There is some risk related to study procedures such as side effects of the dilation and anesthetic drops and general anesthesia risks like mouth or throat pain, injury to mouth or teeth, allergic reaction to anesthetic etc.
The CorNeat KPro can provide visual rehabilitation for severely diseased corneas at high risk for failure with traditional corneal transplantation.
The CorNeat KPro may reduce the major risks that Keratoprosthesis surgery holds such as corneal melt, elevation of intraocular pressure and endophthalmitis.
Moreover, implantation of CorNeat KPro may provide the patients with improved visual quality as compared to current solutions.

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

1. Male or female aged >= 18 and <= 80 years on the day of screening
2. Candidates must have the ability and willingness to attend all scheduled visits and comply with all study procedures
3. Keratoprosthesis surgery is indicated in cases when keratoplasty is not a reasonable option or following a verifiable history of prior failed corneal transplantation.
4. Indications that fall under poor candidate for keratoplasty include but are not limited to: herpetic keratitis, vascularized corneal scar, Ocular Cicatricial Pemphigoid, chemical or thermal burn, Steven Johnson Syndrome, and limbal stem cell deficiency;
5. Adequate tear film and lid function
6. Perception of light in all quadrants

7. Female patients of childbearing age must have negative pregnancy test at screening and agree to use an effective method of contraception throughout the study

Exclusion criteria

1. Reasonable chance of success with traditional keratoplasty
2. Current retinal detachment
3. Connective tissue diseases or severely scarred conjunctiva in the target eye
4. End stage glaucoma or evidence of current uncontrolled glaucoma
5. History or evidence of severe inflammatory eye diseases (i.e. uveitis, retinitis, scleritis)
6. Active inflammation of the conjunctiva in one or both eyes
7. History of ocular or periocular malignancy
8. History of extensive keloid formation
9. Any known intolerance or hypersensitivity to topical anaesthetics, mydriatics, or component of the device, specifically acrylate
10. Signs of current infection, including fever and current treatment with antibiotics
11. Severe generalized disease that results in a life expectancy shorter than a year
12. Any clinical evidence that the investigator feels would place the subject at increased risk with the placement of the device
13. Currently pregnant or breastfeeding
14. Participation in any study involving an investigational drug or device within the past 30 days or 5 half-lives of the drug (whichever longer) or ongoing participation in a study with an investigational drug or device
15. Intraoperative complication that would preclude implantation of the study device.
16. Vulnerable populations.
17. Active orbital, scleral or corneal inflammation
18. Hemoglobin A1C (HbA1c) higher than 8% at screening indicating unbalanced diabetes and/or target organ damage associated with diabetes
19. Patients requiring anticoagulation treatment, which cannot be interrupted for the surgical procedure
20. Ocular ischemic syndrome
21. Severely scarred conjunctiva

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2021
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	CorNeat KPro
Registration:	No

Ethics review

Approved WMO

Date:	15-10-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	12-08-2022
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
ClinicalTrials.gov	NCT04485858
CCMO	NL75316.000.21