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Intracorneal prosthesis for corneal blindness

Submission date
20/01/2026

Recruitment status
Recruiting

Registration date
23/01/2026

Overall study status
Ongoing

Last Edited
22/01/2026

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The cornea is a transparent, avascular tissue that continues posteriorly with the sclera to form the outermost layer of the eye. The cornea acts as a barrier against infection and mechanical damage to the internal structures of the eye. Furthermore, the cornea and tear film are responsible for approximately 3/4 of the total refractive power of the eye. Numerous infectious, inflammatory, and degenerative diseases can cause loss of corneal transparency, partially or completely compromising visual function. In these patients, the only therapeutic option for visual rehabilitation is replacement of the diseased cornea with a similar portion of viable and transparent tissue from a donor cornea (keratoplasty). The idea of replacing diseased tissue with an artificial cornea (corneal prosthesis) was first introduced in 1789 by the French ophthalmologist Guillaume Pellier de Quengsy. Since then, many corneal prostheses have appeared and subsequently disappeared from the ophthalmological scene. Intra-Ker is a biocompatible polymethyl methacrylate (PMMA) intracorneal prosthesis consisting of an optical septum acting as a lens, to light radiation to reach and form a focused image on the retina. It is equipped with three arms extending outward to anchor the intracorneal prosthesis within the recipient cornea. For implantation, the intracorneal prosthesis is (1) inserted between two central portions of corneal stroma derived from the posterior portion of two donor corneas, including Descemet's membrane and devoid of endothelium, to isolate the intracorneal prosthesis from contact with the external environment of the eye (anteriorly) or with the anterior chamber of the eye (posteriorly); (2) positioned in the central portion of the recipient patient's cornea, replacing the diseased tissue.

Who can participate?
Patients with unilateral or bilateral corneal blindness for whom a corneal transplant is not indicated due to a short-to-medium term poor prognosis (high-risk transplant).

What does the study involve?
For the restoration of visual function, eligible patients who consent to participate in the study will undergo corneal surgery with implantation of the Intra-Ker intracorneal prosthesis, a long-term, surgically invasive synthetic medical device without CE marking, classified as a Class IIb risk device.

The total duration of the study will take approximately 20 months, including 6 months for patient enrollment, 12 months from surgery (patient retention in the clinical investigation), 1 month for data analysis and 1 month for reporting.

What are the possible benefits and risks of participating?
By participating in the study, the patients will have the opportunity to be treated with a medical device, the Intra-Ker intracorneal prosthesis, which could be decisive in restoring their vision and they will contribute to the development of corneal prostheses for the treatment of corneal blindness when traditional corneal transplantation is no longer indicated.
The use of the Intra-Ker keratoprosthesis in a small number of people with this condition (pilot study) has shown that the new treatment/procedure has no severe side effects, and there is preliminary evidence that some of the patients who underwent the procedure benefited from it. It is therefore possible, but not proven, that the treatment will improve thecondition.

By participating in the study, there is a risk that the treatment may not be effective and that it may not be possible to improve the visual acuity due to complications related to the implant of the prosthesis (formation of intraocular retroprosthetic inflammatory membranes; prosthesis extrusion; ulceration and breakdown of corneal tissue) that require further surgery.

The study provides for careful monitoring of each of these reactions and, if necessary, further surgery. In addition to those related to keratoprosthesis mentioned above, other significant adverse reactions known for the investigational treatment are those related to eye surgery and subsequent post-surgical therapy: allergic reaction to anesthesia, infection, hypotony, hypopyon, hypoema, hemovitreous, expulsive hemorrhage, choroidal hemorrhage, inflammation near a suture requiring surgical treatment, choroidal detachment, retinal rupture or detachment, cystoid macular edema, vitreous, retinal, or subretinal hemorrhage, pupil irregularities associated with structural defects of the iris, infectious endophthalmitis, uveitis, sterile vitreitis, vitreous incarceration, onset or progression of glaucomatous optic neuropathy, adverse events related to drugs and/or interactions with drugs or pre-existing medical conditions.

Where is the study run from?
The study will be run in three different Italian hospitals: Azienda Ospedaliero-Universitaria of Ferrara, Ospedali Privati Forlì
and the Azienda Ospedaliero-Universitaria “Renato Dulbecco” of Catanzaro.

When is the study starting and how long is it expected to run for?
December 2025 to August 2027.

Who is funding the study?
Veneto Eye Bank Foundation, Italy.

Who is the main contact?
Dr Diego Ponzin, diego.ponzin@fbov.it

Contact information

Type(s)
Scientific

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PRIN 2022 PNRR

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IT-25-09-054322

Study information

Scientific Title
Safety and efficacy of an intracorneal prosthesis in patients with corneal blindness

Acronym
INTRAKER

Study objectives
The primary objective of the clinical investigation is to assess the safety of Intra-Ker in terms of the percentage of adverse events and applied device defects within the scope of the intended use.

In the literature, the studies describing the results obtained with the implant of Boston keratoprostheses show a high incidence of complications. In particular, the transcorneal nature of the prostheses used to date involves the intraocular exposure of non-biological material that is responsible for a continuous inflammatory stimulus. This results mainly in a foreign-body reaction with formation of intraocular retroprosthetic inflammatory membranes, which can compromise the drainage channels from the anterior chamber and pathologically raise the intraocular pressure.

To assess the safety of the application of Intra-Ker in terms of:
- Occurrence of adverse events and intracorneal prosthesis defects
- Improvement of visual acuity.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/07/2025, Comitato Etico Area Vasta Emilia Centro (Segreteria locale per Ferrara del CET-AVEC - Ufficio Ricerca e Innovazione Azienda Ospedaliero Universitaria di Ferrara Via Aldo Moro, 8, Ferrara, 44124, Italy; +390532236199; comitatoetico@ospfe.it), ref: 351/2025/Disp /AOUFe

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Assessment of the safety of the application of Intra-Ker

Study type(s)

Health condition(s) or problem(s) studied
Corneal blindness

Interventions
Based on the frequency of retroprosthetic inflammatory membranes formation after intraocular prosthesis implant (24.8% in an average follow-up period of 8.5 months), the sample size was estimated that, based on the one-tailed binomial test, assuming a 5% incidence of this complication after Intra-Ker implant, results as 27 eyes to obtain an alpha level 0.025 with a statistical power of 80%. The total number of patients to be included in the study will be increased to 30 to account for a possible 10% drop-out.

Patients undergo 12 ophthalmic examinations, one before surgery (T0) and after 1, 2, 3, 7, 14, and 21 days and after 1, 2, 3, 6, and 12 months from the implantation of the intracorneal prosthesis. At each visit, each lasting approximately 30 minutes, non-invasive instrumental eye exams will be performed. These are part of the standard care approach for patients with corneal disease and are all mandatory for the trial. However, the surgical implantation of the Intra-Ker intracorneal prosthesis (lasting approximately 1 hour) is not part of the standard care approach.

The safety and efficacy assessments of the prosthesis will include:
- the initial examination (with measurement of vital signs, blood pressure, heart rate, and body temperature), physical examination of both eyes, and a quality of life questionnaire;
- the post-surgical visits will include: measurement of vital signs, ongoing topical and systemic therapies,
- efficacy assessment (vision measurement, questionnaire on daily activities), and safety assessment (slit-lamp eye examination, optical coherence tomography of the anterior and posterior segments, assessment of adverse events and medical device defects, and color fundus photography).

The procedure for the Intra-Ker prosthesis implantation is the following: the surgical procedure during which the keratoprosthesis is inserted into the central portion of the corneal stroma, replacing the diseased tissue. This procedure is performed along with two healthy corneal scaffolds obtained from the posterior portion of two donor corneas, including the Descemet membrane and devoid of endothelium. These scaffolds serve to isolate the intracorneal prosthesis from contact with the outside of the eye (at the anterior portion) and the anterior chamber (at the posterior portion). This ensures that the prosthesis remains intracorneally positioned. Patients may remain hospitalized for the first 3 days after surgery.

The total study duration for the clinical investigation is 12 months from the surgery date. The study is conducted in ophthalmic clinical centres by ophthalmologists with extensive experience in the treatment of ocular surface disorders and corneal grafts.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Intra-Ker

Primary outcome(s)
1. Incidence of intraocular retroprosthetic inflammatory membrane formation, starting from the first month after surgery until the end of the study period, measured using a slit-lamp eye examination and optical coherence tomography eye examination at each visit at baseline before surgery (T0) and after 1, 2, 3, 7, 14, and 21 days and after 1, 2, 3, 6, and 12 months from the implantation of the intracorneal prosthesis

Key secondary outcome(s))
1. Percentage of patients showing improvement in vision of at least one line of visual acuity measured using a Snellen chart at baseline and 12 months

Completion date
09/08/2027

Eligibility

Key inclusion criteria
1. Age ≥ 18 years old
2. Presence of light perception
3. Residual visual acuity limited to 1/10 (20/200) or worse
4. Clinical history of at least 2 keratoplasties of any type, performed for any indication and consecutively failed
5. Intraocular pressure ≤ 22 mm Hg
6. Understanding of the clinical investigation scope and procedure and consent to participation.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Clinical history of ocular and/or systemic diseases that could interfere with the effects of the study treatment or their evaluation (e.g., severe diseases of the ocular surface, severe diseases of the optical nerve, occlusion of the central retinal vein or artery, severe degenerative retinal alterations, retinal detachment, severe amblyopia, pthisis bulbi, etc.)
2. Any condition preventing the understanding or communication of informed consent, study requirements and test protocols, among which cognitive decline, including diagnosed forms of

progressive neurological disease, psychiatric disease, deafness
3. Previous implant of other corneal prosthesis
4. Non acceptance of the study assessments and procedures
5. (For female subjects) pregnancy, breastfeeding or intention of planning a pregnancy in the study period
6. Ongoing participation, or participation in the 30 days before study enrolment, to any clinical study with investigational drug or medical device in the field of ophthalmology
7. Conditions that could limit the lifespan to less than 1 year from inclusion.

Date of first enrolment
09/12/2025

Date of final enrolment
09/06/2026

Locations

Countries of recruitment
Italy

Study participating centre
Azienda Ospedaliero-Universitaria di Ferrara
Via A. Moro, 8
Ferrara
Italy
44124

Study participating centre
Ospedali Privati Forlì
A. Gramsci, 42
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Study participating centre
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Sponsor information

Organisation
Veneto Eye Bank Foundation

ROR
https://ror.org/02qexn916

Funder(s)

Funder type

Funder Name
Veneto Eye Bank Foundation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0.2	05/07/2026	22/01/2026	No	Yes
Protocol file	version 0.2	05/07/2026	22/01/2026	No	No