ISRCTN17771283 https://doi.org/10.1186/ISRCTN17771283

Investigating the safety and improvement of vision for patients suffering from severe keratoconus or post LASIK ectasia after treatment with the Xenia corneal lenticule

Submission date 02/12/2021	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol
Registration date 01/03/2022	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 13/04/2026	**Condition category** Eye Diseases	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Keratoconus and post-LASIK ectasia are progressive disorders characterized by thinning and distortion of the cornea of the eye, causing it to bulge and leading to a loss of visual function (eyesight). There are various options available for improving sight in mild to moderate stages of the disorder such as using a type of contact lens. However, in cases of advanced stages, or if for some reason inability to wear contact lenses, no acceptable improvement of sight can be achieved with contact lenses. In such conditions surgery to correct the problem may be considered.

For the treatment of severe keratoconus and post-LASIK ectasia, several treatment options are available. However, in some people, the risk of complications or some of the treatments not working in the long-term seem higher or they may be associated with potential risks of infection, perforation, and other adverse reactions. Finally, if no other options are feasible or possible, transplantation of a human donor cornea might be possible. Again, this treatment is highly invasive and represents significant risks such as transplant rejection and a complete loss of vision.

Other ways have been considered for treatment such as just replacing a portion of the cornea including other types of implantable collagen to treat these conditions. Researchers are looking for such implants to stop the progression of the disease even in advanced stages, and to postpone or even avoid the need for corneal transplantation.

For the purpose of this study, an innovative corneal implant called the Gebauer™ Lenticule will be used to treat severe keratoconus or post-LASIK ectasia. The Gebauer™ Lenticule is a type of corneal implant, made from a substance called collagen from an animal. The Gebauer™ Lenticule implant is a disc-shaped piece of see-through, highly purified, and stable corneal collagen fibres from a pig. It will be implanted into the diseased eye and is expected to improve the stability of the cornea while not impairing the vision.

We currently would only consider to implant the Gebauer™ Lenticule after other treatment options have been exhausted. The procedure is reversible, as the implant can be removed in the unexpected case of an adverse reaction, and the initial vision from before the implantation can be restored. Due to the transparency of the cornea, the implant can be seen and inspected at all times, which is beneficial to check on it.

The purpose of this study is to look at how well the implant is tolerated, its safety, and how effective this new treatment option is in the treatment of keratoconus or post-LASIK ectasia. This is not a first-in-human study, but currently, the implant has only been used in a small number of patients (approximately 17) so it is still a very new treatment.

Who can participate?
Patients aged between 18 and 80 years old who have a diagnosis of severe keratoconus or post-LASIK ectasia and would prefer to avoid corneal transplant surgery or penetrating keratoplasty.

What does the study involve?
Before treatment with the GebauerTM Lenticule, the doctor will decide suitability to take part. The doctor will perform a detailed ophthalmological investigation. If the criteria are met and informed consent to participate in this study is given, the patient can participate. The length of study participation will be 6 months. In addition to that, up to 2 further long-term follow-up visits after 1 and 2 years are currently planned. All participants in the study will undergo the Gebauer™ Lenticule implantation. Participants will have a series of telephone and clinic follow-up visits where ophthalmic examination of the eye and Lenticule will take place.

What are the possible benefits and risks of participating?
The Gebauer™ Lenticule has several advantages in treating keratoconus or post-LASIK ectasia as the Gebauer™ Lenticule corneal implant device is a custom-made device intended for patients suffering from keratoconus or post-LASIK ectasia. The GebauerTM Lenticule is a see-through, compatible corneal implant for humans. Treatment with the device is safe and this study will hopefully show the implant will stop the diseased cornea from getting worse, without impairing vision or pressure in the eye.

The implanted collagen fibers are similar to the collagen fibers present in the natural human corneal tissue. Therefore, the implant material is expected to not be rejected by the body and the risk of rejection of it is much lower than for human cornea donor tissue transplantation.

The risks associated with participation in this study are similar in nature and severity to those encountered with other corneal surgeries. These risks include anterior or posterior synchie; cornea abrasion and opacity; device detachment and requirement of further surgical manipulation; cornea thinning and perforation; intraocular pressure elevation due to procedure or steroids; infection; inflammation; cataract induction; retinal detachment; and device rejection.

In previous studies, 17 patients have received this treatment, and 90% patient satisfaction and stable and clear lenticules over a 6-month follow-up period were reported.

If the implant needs to be removed, for example, if the implant is not tolerable, the procedure is reversible and the initial vision from before the implantation can be restored. The potential risks involved in removing the device are the same as any other small-incision keratoplasty procedures. There are no known additional risks as sight will be restored.

The implant may be inserted immediately after the pocket creation or delayed up to several months later with confidence. The pocket created can be opened up and re-accessed safely

several months following insertion. Re-opening and re-accessing the pocket is a relatively safe procedure within several months of the initial surgery, usually with no significant change to vision provided there were no other complications such as infection and inflammation to impact on vision. If the implant is removed, vision will most likely return to what it was before the initial surgery.

Where is the study run from?
New Cross Hospital (UK) and the Optimax Laser Clinic Leicester (UK)

When is the study starting and how long is it expected to run for?
From January 2019 to December 2026

Who is funding the study?
Gebauer Medizintechnik GmbH (Germany)

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04741230

Integrated Research Application System (IRAS)
279594

Central Portfolio Management System (CPMS)
45845

Study information

Scientific Title
Prospective, investigator-initiated feasibility study to evaluate the safety, and indicative effectiveness of Gebauer™ lenticules in patients suffering from severe keratoconus or post LASIK ectasia

Study objectives
Treatment with the Gebauer™ Lenticule is safe and results in improvement of vision by stabilizing the cornea and improving the refractive regularity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/2021, Sheffield REC (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ; +44 (0)207 1048224; sheffield.rec@hra.nhs.uk), ref: 20/YH/0176

Primary study design
Interventional

Study design
Non-randomized study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe keratoconus or post-LASIK ectasia

Interventions
Once the participant meets recruitment criteria, a Femtosecond Laser will be used to create a 3 mm stromal pocket. The Xenia Lenticule will be inserted intra-stromally via the 3 mm pocket. Patients will be treated with antibiotics and anti-inflammatory eye drops for 2 weeks and will be followed up at 1 day, 4 weeks, 3 months, 1 year, and 2 years, as well as with telephone consultations whenever needed. The participant will have regular clinical assessments to review the implant and condition of the eye, and will include:
1. Intraocular pressure (IOP) measurement
2. Best corrected visual acuity
3. Corneal transparency (slit lamp)
4. Lenticule transparency (slit lamp)
5. Photodocumentation of corneal status
6. Inflammation of cornea or sclera
7. Signs of immunological rejection
8. Central corneal thickness measurement (OCT)
9. Corneal topography (K-reading map)
10. Assessment of corneal epithelium
11. Assessment of conjunctiva
12. Assessment of iris/pupil
13. Assessment of Lens
14. Assessment of ocular pain
15. Assessment of patient satisfaction

16. Assessment of conjunctiva
17. Assessment of iris/pupil
18. Assessment of lens
19. Assessment of ocular pain
20. Assessment of patient satisfaction with treatments and outcome
In addition to that, safety monitoring will be performed (recording of adverse events and medications).

Intervention Type
Other

Primary outcome(s)
1. Signs of immunological rejection during the post-implantation observation period measured using a slit-lamp microscope once between 1-3 days
2. Frequency and severity of all treatment-related adverse events, during implantation of the Gebauer™ Lenticule and throughout the post-implantation observation period measured from safety monitoring records once between 1-3 days, at 14, 28, 42, 56, 70, and 84 days, and at 3, 6, 12, and 24 months
3. Microscopic examination of the eye using a slit-lamp at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
4. Corneal topography measured using Sirius Scan at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
5. Corneal thickness measured using Sirius scan at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
6. Patient satisfaction with received treatments and outcome measured using the Patient Satisfaction Survey Questionnaire once between 1-3 days, at 14, 28, 42, 56, 70, and 84 days, and at 3, 6, 12, and 24 months

Key secondary outcome(s)
1. Changes in intraocular pressure (IOP) during observation period measured using Goldmann Tonometry examination once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
2. Changes in corneal transparency and lenticule transparency during observation period measured using a slit-lamp microscope once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
3. Microscopic examination of the eye using a slit-lamp microscope at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
4. Vision measured using a Snellen/LogMar Chart at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
5. Inflammation of cornea or sclera during observation period measured using a slit-lamp microscope at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
6. Changes to the corneal epithelium during observation period measured using a slit-lamp microscope at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
7. Changes to the conjunctiva, iris/pupil, and lens during observation period measured using a slit-lamp microscope at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
8. Changes to ocular pain/discomfort during observation period measured using a slit-lamp microscope at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
9. Best-corrected visual acuity during the observation period measured using a Snellen/LogMar Chart at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12, and 24 months
10. Investigator’s overall procedure evaluation measured using assessment of patient's unaided and best-corrected visual acuity at baseline, once between 1-3 days, at 28 days, and at 3, 6, 12,

and 24 months
11. Suitability of pocket size measured using examination with operating microscope at day 0
12. Duration of surgical procedure measured using examination with operating microscope at day 0
13. Requirement of specific post-surgical measures (suturing after implantation, bandage contact lens, antibiotic and
immunosuppressive treatments) measured using a slit-lamp microscope and patient notes once between 1-3 days and at 14 days

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Diagnosis of either of the following:
1.1. Severe keratoconus in patients who would prefer to avoid corneal transplant surgery /penetrating keratoplasty
1.2. Diagnosis of severe post-LASIK Ectasia in patients who would prefer to avoid corneal transplant surgery/penetrating keratoplasty.
2. Free of diagnosed terminal illnesses (life expectancy of ≥2 years)
3. Aged ≥18 years and <80 years
4. Patients' contact lenses must have been removed at least one-week prior to surgery for soft lenses and two weeks prior to surgery for hard lenses
5. Understands the study requirements and the treatment procedures and provides written Informed Consent before any study-specific tests or procedures are performed
6. Able and willing to complete all study visits and comply with the study-specific requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. History or presence of any ocular pathologies that may interfere with the planned surgical treatment, including corneal epithelial problems
2. Previous corneal transplantation or corneal implant in the designated eye
3. Cataract with anticipated surgical intervention (IOL implantation) within 2 years
4. Active inflammation and/or infection of the eye or the eyelid
5. IOP <10 mmHg or >21 mmHg
6. Professionally diagnosed and currently treated autoimmune diseases
7. Current strong symptoms of any allergy
8. History of major organ transplantation and/or current continuing immunosuppressive treatment
9. History of blood transfusion within the last 12 months
10. Currently participating or has participated in another investigational clinical study within the past 60 days
11. Pregnancy and lactation

Date of first enrolment
01/06/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
Optimax Laser Eye Clinic (leicester)
171-173 Charles Street
Leicester
England
LE1 1LA

Sponsor information

Organisation
The Royal Wolverhampton NHS Trust

ROR
https://ror.org/05pjd0m90

Funder(s)

Funder type
Industry

Funder Name
Gebauer Medizintechnik GmbH

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 1.6	03/08/2021	25/02/2022	No	No