

Compassionate Use Study of Epi-ON Corneal Collagen Crosslinking Performed Using UVA Exposure on Eyes With Ectatic Corneal Diseases for Subjects With Down Syndrome

NCT07135167

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| Status | RECRUITING |
| Phase | Phase 3 |
| Sponsor | Woolfson Eye Institute |
| Enrollment | 225 participants |

Key Eligibility Criteria

Inclusion (6)

- Be at least 8 years of age or older, male or female, of any race.
 - Have a diagnosis of Down syndrome or other cognitive, developmental, or medical conditions that precludes the subject from reliably following instructions or performing some of the study examination procedures.
 - Have a diagnosis of keratoconus, pellucid marginal degeneration, progressive ectasia after previous CXL treatment, other ectatic condition, or forme fruste keratoconus based on topography, tomography, and slit lamp examination.
 - Provide written informed consent and a signed HIPAA form. Pediatric subjects less than 14 years of age must sign an assent, and a parent or legal guardian must sign an informed consent. If the subject has impaired consent capacity, determined by the consentor, the consent form must be signed by the subject's legally authorized representative on behalf of the subject.
 - Satisfactory completion of the standardized clinical decision tool evaluation of patient suitability for CXL. (See Section 7.2.3)
- ... and 1 more (see full listing online)

Exclusion (12)

- Normal corneal topography.
 - A history of previous corneal transplant in the study eye.
 - Minimum corneal thickness ≤ 300 (measured by Pentacam and Ultrasound) at the screening exam.
 - Previous ocular condition (other than refractive error) in the eye(s) to be treated that may predispose the eye to future complications or prevent the possibility of improved vision, for example:
 - History of, or active, corneal disease (e.g., herpes simplex, herpes zoster keratitis, etc.)
- ... and 7 more (see full listing online)

Locations (12 total)

Woolfson Eye Institute, Atlanta, Georgia, United States
Woolfson Eye Institute, Atlanta, Georgia, United States
Woolfson Eye Institute, Canton, Georgia, United States
... and 9 more locations