Safety and Effectiveness of the PXL-Platinum 330 System for Corneal Cross-Linking

NCT03918408

Status	RECRUITING
Phase	Phase 1
Sponsor	Pacific Clear Vision Institute
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (31)

- Subjects who have one or both eyes that meet criteria 1 \& 2 and 1 or more of the following criteria will be considered candidates for this study.
- years of age or older
- Evidence of progressive keratoconus (based on the discretion of the physician as evidenced by an increase in astigmatism, asymmetry, or worsening vision in the last 3 or more months)
- Presence of central or inferior steepening.
- Axial topography consistent with keratoconus

... and 26 more (see full listing online)

Exclusion (10)

- Eyes classified as either normal or atypical normal on the severity grading scheme.
- Corneal pachymetry at the screening exam that is \<330 microns at the thinnest point in the eye(s) to be treated.
- Previous ocular condition (other than refractive error) in the eye(s) to be treated that may predispose the eye for future complications, for example:
- History of or active corneal disease (e.g., herpes simplex, herpes zoster keratitis, recurrent erosion syndrome, acanthomeoeba, etc.)
- Clinically significant corneal scarring in the CXL treatment zone that is not related to keratoconus or, in the investigator's opinion, will interfere with the cross-linking procedure.

... and 5 more (see full listing online)

Locations (1 total)

Pacific Clear Vision Institute, Eugene, Oregon, United States