First in Human Study to Assess Safety and Efficacy of an Implantable Nitinol Device in the Treatment of Keratoconus

NCT06451718

Status	RECRUITING
Phase	Not Applicable
Sponsor	Recornea Srl
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (11)

- Signed and dated informed consent form.
- Male and female e 18 years old.
- Not recommended for ICRS.
- Recommended for keratoplasty.
- Minimum corneal thickness e 350µ.

... and 6 more (see full listing online)

Exclusion (6)

- Inability of patient and/or relatives to understand the clinical investigation procedures and thus inability to give informed consent.
- Untreated progressive KC.
- Single functioning eye.
- Other ocular diseases (eyelids malposition, uveitis, ocular hypertension, glaucoma, cataract, retinal disorders) or corneal surgeries (refractive corneal surgery, keratoplasty), except corneal crosslinking.
- Systemic collagenopathies and/or vasculitis, and other diseases that in the opinion of the principal Investigator, may be contraindicated.

... and 1 more (see full listing online)

Locations (2 total)

Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma, Roma, Italy
Instituto de Microcirugía Ocular de Barcelona (IMO), Barcelona, Bar, Spain