

Customised topographic photorefractive keratectomy (PRK) followed by corneal cross-linking in a single procedure for progressive keratoconus

Submission date 22/12/2009	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 18/02/2010	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/02/2010	Condition category Eye Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

Comparison of cross linking alone and customised photorefractive keratectomy (PRK) followed by cross linking in the treatment of progressive keratoconus: a prospective non-randomised single centre trial

Study objectives

Cross linking is a well established procedure to halt the progression of keratoconus. Customised topographic photorefractive keratectomy (PRK) worked well in the correction of irregular astigmatism. The combination of these two procedures should be a valuable tool for both the correction of corneal irregularity and the prevention of progression in case of progressive keratoconus.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committee of Azienda Ospedaliera Policlinico di Bari approved on the 18th June 2008

Primary study design

Interventional

Study design

Prospective non-randomised single centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Keratoconus

Interventions

Customised topographic PRK and corneal cross-linking in a single procedure are performed in the worse keratoconic eye, while routine cross linking is performed on the fellow eye.

The treatment lasts about 55 minutes (about 30 seconds for PRK and 50 minutes for cross-linking procedure). The duration of follow-up is 18 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Measured at 1, 3, 6, 12, and 18 months:

1. Visual acuity
2. Refraction
3. Corneal aberrations
4. Corneal topography

Key secondary outcome(s)

Measured at 1, 3, 6, 12, and 18 months:

1. Confocal microscopy
2. Anterior segment optical coherence tomography

Completion date

08/01/2011

Eligibility

Key inclusion criteria

1. Documented progressive keratoconus
2. Corneal thinnest point: 450 micra
3. Hard contact lens and full spectacle correction intolerance
4. Aged over 18 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Corneal thinnest point less than 450 micra
2. History of ocular morbidity
3. Previous ocular surgery

Date of first enrolment

26/06/2008

Date of final enrolment

08/01/2011

Locations

Countries of recruitment

Italy

Study participating centre

Piazza Giulio Cesare 11

Bari

Italy

70124

Sponsor information

Organisation

Azienda Ospedaliera Policlinico di Bari (Italy)

ROR

<https://ror.org/00pap0267>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Azienda Ospedaliera Policlinico di Bari (Italy) - Department of Ophthalmology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration