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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Prospective non-randomised single centre trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Non available in web format, please use the contact details below to request a patient information sheet

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 measure
Measured at 1, 3, 6, 12, and 18 months:
1. Visual acuity
2. Refraction
3. Corneal aberrations
4. Corneal topography

Secondary outcome measures
Measured at 1, 3, 6, 12, and 18 months:
1. Confocal microscopy
2. Anterior segment optical coherence tomography

Overall study start date
26/06/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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)

Sponsor details
c/o Giovanni Alessio
Department of Ophthalmology
Piazza Giulio Cesare, 11
Bari
Italy
70124

Sponsor type
Hospital/treatment centre

Website
http://www.policlinico.ba.it/sito/index.php

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration