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PENTACON Trial: Partial ENdothelial Trepanation in Addition to Anterior Lamellar Keratoplasty in keratoCONus

Submission date 16/06/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 11/08/2010	**Overall study status** Completed	
Last Edited 24/07/2020	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01145937

Protocol serial number
30756.041.10

Study information

Scientific Title
Partial endothelial trepanation in addition to anterior lamellar keratoplasty in keratoconus: a randomised controlled open-label parallel interventional trial

Acronym
PENTACON

Study objectives
To investigate the additional value of partial endothelial trepanation (PET) in an anterior lamellar keratoplasty (ALKP) procedure in terms of efficacy and safety in patients with keratoconus, compared in a randomised clinical trial with a regular ALKP procedure.

Please note that as of 18/06/2013, the following changes were made to the trial record:
1. The anticipated start date was updated from 01/07/2010 to 01/03/2011
2. The anticipated end date was updated from 01/05/2013 to 01/05/2015

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medisch Etische Toetsings Commissie (Medical Ethical Approval Board) of University Medical Center Utrecht approved on the 25th April 2010 (ref: 30756.041.10)

Study design
Randomised controlled open-label parallel interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Keratoconus

Interventions
Peroperative corneal perforation is the biggest drawback of currently utilised grafting procedures (ALKP, 20 - 30%). Our new technique is believed to be safer, by reducing the number of corneal perforations during surgery. Corneal perforation necessitates converting the procedure to a full-thickness graft with a less favourable long term rejection profile.

To circumvent this perforation problem we utilise a method in which, in addition to an anterior lamellar keratoplasty (ALKP), a partial endothelial trepanation (PET) is performed. This technique was first performed by Massimo Busin, Villa Serena Hopsital, Forli, Italy. The endothelium en Descemet are paracentrally and circular loosened, but some tissue bridges are left in place. This 'island' is able to mould to the healthy donor curvature. By doing this, the

surgeon can retain a safer graft thickness margin leading to a lowered number of preoperative perforations. The addition of PET is believed to make corneal grafting safer and more predictable.

The control group will be treatment with a regular ALKP procedure, using the Big Bubble technique according to Anwar et al.

Patients will be randomly assigned to either group A (PET in addiation to ALKP) or group B (regulare ALKP procedure).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Peroperative corneal perforation

Key secondary outcome(s))
1. Best corrected visual acuity one year post-operation
2. Manifest refraction one year post-operation
3. Contact lens use (soft/rigid/scleral) or spectacle use
4. Self-rated improvement questionnaire
5. Corneal endothelial function one year post-operation
6. Graft rejection rate

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. Aged equal or above 18 years, either sex
2. Keratoconus as defined and classified by:
2.1. Presence of corneal thinning and protrusion on slit-lamp examination
2.2. Topographic criteria according to keratometry, I-S, astigmatism, and skew percentage (KISA%) index (greater than 100%)
2.3. Mean corneal curvature map
3. Decreased best corrected visual acuity due to corneal scarring or contact lens intolerance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Prior corneal surgery, cross linking, refractive surgery or other treatment modalities
2. (Localised) corneal thickness less than 200 µm
3. Associated corneal endothelial disease on specular microscopy as defined by:
3.1. Less than 1500 endothelial cells per mm^2
3.2. Polymegathism greater than 0.3
3.3. Pleomorphism less than 0.6 (all are measurements of endothelial dysfunction)
4. Gross ophthalmic pathology surpassing keratoconus as cause of decreased visual acuity
5. Keratoconus-like disease (keratoglobus, pellucid marginal degeneration)
6. Associated corneal anomalies (microcornea, macrocornea, buphthalmos, Peters syndrome, iridocorneal endothelial [ICE]-syndrome, etc.)

Date of first enrolment
01/03/2011

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
Dr. F.P. Fischer Stichting (Netherlands)

ROR
https://ror.org/000zsjk11

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Center Utrecht (UMCU) (Netherlands) - Department of Ophthalmology

Funder Name
Dr. F.P. Fischer Stichting (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration