

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

Submission date 16/06/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/07/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
NCT01145937

Secondary identifying numbers

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 Ethische 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (Dutch only)

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 Hospital, Forli, Italy. The endothelium on Descemet is paracentrally and circularly 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 addition to ALKP) or group B (regular ALKP procedure).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Peroperative corneal perforation

Secondary outcome measures

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

Overall study start date

01/03/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

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)

Sponsor details

Postbus 2756

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Sponsor type

Industry

Website

<http://www.lsbs.nl/uitzicht/uk/>

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

Publication and dissemination plan

Not provided at time of registration

2015 thesis in https://www.researchgate.net/profile/Robert_Wisse/publication/316463878_Keratoconus_-_Inflammatory_associations_and_treatment_characteristics/links/58ffa1eda6fdcc8ed50db964/Keratoconus-Inflammatory-associations-and-treatment-characteristics.pdf (added 24/07/2020)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration