Partial endothelial trepanation in addition to deep anterior lamellar keratoplasty in keratoconus patients. A randomized clinical trial.

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To investigate the additional value of partial endothelial trepanation (PET) in a deep anterior lamellar keratoplasty (DALK) procedure in terms of efficacy and safety in patients with keratoconus.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders congenital
Study type	Interventional

Summary

ID

NL-OMON36229

Source
ToetsingOnline

Brief title
PENTACON trial

Condition

- Eye disorders congenital
- Congenital eye disorders (excl glaucoma)

Synonym
corneal ectasia., keratoconus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Dr. F.P.Fischer-Stichting

Intervention

Keyword: corneal grafting, DALK, keratoconus, ophthalmology

Outcome measures

Primary outcome

Primary outcome is:

* peroperative complications and conversion ratios;

Secondary outcome

Secondary study objectives are:

* best corrected visual acuity one year post op;

* manifest refraction one year post op;

* self-rated improvement questionnaire;

* graft rejection rate;

* corneal endothelial function one year post op.

Study description

Background summary

Keratoconus is a progressive, non-inflammatory corneal disease in which irregular refractive properties of the cornea result in loss of visual acuity. Keratoconus usually arise in adolescence, is bilateral and has an estimated incidence of 1:2000. The aetiology of keratoconus is largely unknown, genetic

predispositions are currently under investigation. Treatment is aimed at improving vision, principally using (rigid) gas permeable contact lenses (RGPs). With progression of the disease non-correctable refractive abnormalities and/or corneal scars arise. For these advanced stages of keratoconus, a corneal transplant is the only treatment modality.

The first corneal transplant for keratoconus was conducted in 1936 by Ramon Castroviejo in New York*s Columbia Presbyterian Medical Centre. Ever since, corneal grafting is subject to many technical developments. For over 70 years, a technique is used in which a circular donor disc is cut with a trephine and sutured in a concordantly prepared recipient, called a perforating keratoplasty (PKP).

With the advent of refractive surgery in the years 1990, equipment appeared to split a cornea in horizontal lamellae. This made partial thickness grafting possible, tailoring grafts according to the nature and location of corneal pathology. For keratoconus, only the affected anterior part of the cornea needs to be transplanted. The posterior (endothelial) part is particularly involved in graft rejections. The chance of graft rejection decreases significantly when the patient*s endothelium is left in place.
For keratoconus, this new treatment modality is called a deep anterior lamellar keratoplasty (DALK). The transplanted anterior corneal thickness is maximized, and the patient retains its own endothelium and Descemet membrane, leading to lower graft rejection rates. Theoretically, one could expect lower cataract formation rates as well.

The biggest drawback of a DALK procedure is the risk of inadvertent peroperative corneal perforation. The lamellae is cut too thick necessitating a conversion to a complete thickness graft similar to a regular PKP. To prevent inadvertent perforation, several techniques are described to dissect the stroma from the posterior lying Descemet membrane and corneal endothelium.Failure and perforation are described in 20% of cases though, leading to poor surgical predictability and leaving the patient with an inferior end product.

To circumvent this problem we utilize a method in which, in addition to a DALK, a partial endothelial trepanation (PET) is performed. This technique was first performed by Busin, Villa Serena Hopsital, Forli, Italy. The endothelium is loosened, but not transplanted. By doing this, the surgeon can retain safer graft thickness margins leading to a lowered number of preoperative perforations. The cornea is enabled to *mould* to the healthy donor curvature. The addition of PET is believed to make corneal grafting safer and more predictable.

Study objective

To investigate the additional value of partial endothelial trepanation (PET) in a deep anterior lamellar keratoplasty (DALK) procedure in terms of efficacy and

safety in patients with keratoconus.

Study design

A randomized controlled interventional parallel group patient-blinded trial. Patients will be randomly assigned to either group A (addition of partial endothelial trepanation to a deep anterior lamellar keratoplasty (PET+DALK procedure) or group B (conventional DALK procedure).

Intervention

Patients undergo, after thorough ophthalmic screening, a corneal grafting procedure according to the DALK (deel anterior lamellar keratoplasty) technique, with or without the addiation of the investigated PET (partial endothelial trepanation) technique. The peroperative and postoperative care for both treatmentgroups are identical.

Study burden and risks

The benefit for the keratoconus patient is regaining better visual acuity when contact lens correction has become insufficient. Irregular astigmatism is the main contributing factor for loss of visual acuity and can often be corrected by rigid gas permeable contact lenses (RGPs) in early stages. With the advancement of the keratoconus, the shape of the cornea prohibits proper contact lens fitting, leading to contact lens intolerance. A keratoplasty will reform the corneal curvature and will help in regaining good vision. Especially in the case of corneal scarring in advanced keratoconus, corneal transplantation is the only method to regain good clarity of the cornea. We expect the modern PET+DALK procedure to surpass traditional keratoplasty in terms of efficacy and safety.

The patient burden is comparable to the experiences of current transplant methods used. Preoperatively, patients undergo a full ophthalmic screening. A corneal transplant is performed under general anaesthesia and takes around 120-180 minutes. Postoperative checks are done at 1 day, 1 week, 2 weeks, 4 weeks, 6 weeks, 3 months, 6 months and annually thereafter. This control scheme is in line with the guidelines of the Dutch Organ Transplantation Registry (NOTR). The first weeks patients receive antibiotic / steroid eye drops in decreasing frequency and will have to keep to certain precepts. These precepts include, but are not limited to, refraining from heavy physical activities, wetting of the eye and swimming for a certain amount of time. The inserted corneal sutures are removed in two tempi, after 6 and 12 months.

Treatment risks do certainly exist, but are comparable with current transplant methods. Short term side effects include postoperative wound infection, wound dehiscence (necessitating suture removal or re-suturing), uveïtis, ocular

hypertension and hypersensitivity to ophthalmic medications. Long term risk includes irregular astigmatism necessitating contact lens correction, cataract formation, glaucoma, graft rejection, and graft failure.

Study participation or randomization have no effect on corneal graft selection and quality.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- age equal or above 18 years
- keratoconus as defined by
presence of corneal thinning and protrusion on slit-lamp examination
topographic criteria according to KISA% index

- decreased best corrected visual acuity due to corneal scarring or contact lens intolerance

Exclusion criteria

- prior corneal surgery, cross linking, refractive surgery or other treatment modalities
- associated corneal endothelial disease
- gross ophthalmic pathology surpassing keratoconus as couse of decreased visual acuity

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2012
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	21-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-11-2011

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN39068025
CCMO	NL30756.041.10