More efficient use of corneal donations: the Dutch Lamellar Corneal Transplantation Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26035

Source
Nationaal Trial Register

Brief title
DLCTS-study

Health condition

Corneal disorders

Sponsors and support

Primary sponsor: ZON-MW, The Netherlands Organization for Health Research and Development.

University Hospital Maastricht, Department of Ophthalmology
Source(s) of monetary or material Support: Algemene Nederlandse Vereniging Ter voorkoming van Blindheid.

Nederlandse Vereniging van Blinden en Slechtzienden.

Intervention

Outcome measures

Primary outcome

Discard rate of donated corneas.

Secondary outcome

Visual acuity, astigmatism, stray light evaluation, contrast sensitivity, endothelial cell loss, incidence endothelial rejection, vision-related quality of life and patient satisfaction. Before operation, and at 3, 6, 12 months after operation.
A full economic evaluation.

Study description

Background summary

Problem definition:
During the years 1998-2001 the percentage of donated eye tissue in the Netherlands issued for corneal grafting decreased from 50.8% (1998) to 35.2% (2001). In 2001 the Cornea Bank N.O.R.I. Amsterdam processed 2955 donor eyes of which 1040 were actually grafted. The major reasons for the discard rate of 64.8% of donated eye tissue were abnormalities of the anterior corneal stroma and a decreased vitality of the corneal endothelium. The shortage of donor tissue has resulted in an average waiting time for corneal transplantation of 6 months.

Intervention:
New lamellar transplantation techniques that only transplant the anterior side of the cornea (DALK) or the posterior side (PLK) may use previously discarded tissue by transplantation of only the healthy part of the donated corneal tissue. In addition, DALK and PLK may create future possibilities for "double use" of the anterior and posterior side of one donated cornea for two transplantations. The use of DALK and PLK (in 2001 only 2.7% of all transplantations were lamellar keratoplasties) may lead to a more efficient use of donor material and could theoretically decrease the current discard rate of donor tissue of 64.8% to 25% and shorten the waiting time from 6 months to 1 month.

Design:
Two randomized clinical trials (RCT) of DALK vs. PKP and PLK vs. PKP will evaluate cost-effectiveness and medical outcome of the lamellar transplantation techniques.

Outcome measures:
The primary outcome measure is discard rate of donated corneas.
Secondary outcome measures are visual acuity, astigmatism, stray light evaluation, contrast sensitivity, endothelial cell loss, incidence endothelial rejection, vision-related quality of life and patient satisfaction.

Power analysis shows that for an expected reduction of discard rate from 65% to 25% using DALK/PLK techniques 28 patients in each RCT are needed.

Economic evaluation:
A full economic evaluation (FEE) alongside the RCT will be performed.

Time schedule:
Patients will be included during the first 21 months of the study by the participating centers.

Study objective

The use of DALK and PLK may lead to more efficient use of donor material and could theoretically decrease the current discard rate of donor tissue of 64.8% to 25% and shorten the waiting time from 6 months to 1 month.
For PLK, we estimate that the induced postoperative astigmatism by the lamellar transplantation technique will be reduced by 50% as compared to conventional PKP, that the duration of visual rehabilitation (defined as time point where patients are suitable for spectacle prescription) will decrease from 6 to 3 months, that wound dehiscence problems will decrease by 50% and that the incidence of contact lens fitting for high postoperative ametropia and astigmatism will decrease by 75%.
For DALK, we estimate a reduction in postoperative astigmatism of 25% as compared to conventional PKP, a decrease in the duration of visual rehabilitation from 6 to 3 months, a reduction in wound dehiscence problems by 50%, a decrease in the incidence of contact lens fitting for high postoperative ametropia and astigmatism with 50%, a decrease in endothelial rejection rate by 100%, and a decrease in endothelial cell loss from 1 month to 24 months postoperatively of 50%.

Intervention

Group 1:
Deep Anterior Lamellar Keratoplasty compared to Penetrating Keratoplasty.

Group 2:
Posterior Lamellar Keratoplasty compared to Penetrating Keratoplasty.

Contacts

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Eligibility criteria

Inclusion criteria

Deep Anterior Lamellar Keratoplasty:
1. Keratoconus intolerant for contact lens wear, without previous hydrops or Descemet's rupture;
2. Stromal opacification not reaching Descemet's membrane and without concomitant endothelial disease;
3. Best Spectacle Corrected Visual Acuity (BSCVA) < 0.4;
4. Patients who signed the informed consent.

Exclusion criteria

Posterior Lamellar Keratoplasty:
1. Endothelial dysfunction caused by pseudophakic or aphakic corneal edema;
2. (Fuchs') Endothelial dystrophy;
3. BSCVA < 0.4;
4. Without severe scarring of the anterior stromal cornea;
5. Patients who signed the informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2005
Enrollment:	140
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-12-2006
Application type:	First submission

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
NTR-new	NL821
NTR-old	NTR834
Other	: ZonMw-945-04-454
ISRCTN	ISRCTN02191620

Study results

Summary results

Yanny Y.Y. Cheng, MD, Elisabeth, PhD, Rudy M.M.A. Nuijts, MD, PhD.
"Femtosecond Laser assisted Descemet's Stripping Endothelial Keratoplasty."
Journal of Cataract and Refractive Surgery, 2007. In press.