

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

Submission date 26/02/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/02/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/10/2012	Condition category Eye Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ZonMw-945-04-454; NTR834

Study information

Scientific Title

Acronym

DLCTS-study

Study objectives

The use of deep anterior lamellar keratoplasty (DALK) and posterior lamellar keratoplasty (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 six months to one month.

For PLK, we estimate that the induced post-operative astigmatism by the lamellar transplantation technique will be reduced by 50% as compared to conventional penetrating keratoplasty (PKP), that the duration of visual rehabilitation (defined as time point where patients are suitable for spectacle prescription) will decrease from six to three months, that wound dehiscence problems will decrease by 50% and that the incidence of contact lens fitting for high post-operative ametropia and astigmatism will decrease by 75%.

For DALK, we estimate a reduction in post-operative astigmatism of 25% as compared to conventional PKP, a decrease in the duration of visual rehabilitation from six to three months, a reduction in wound dehiscence problems by 50%, a decrease in the incidence of contact lens fitting for high post-operative ametropia and astigmatism with 50%, a decrease in endothelial rejection rate by 100%, and a decrease in endothelial cell loss from one month to 24 months post-operatively of 50%.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, active controlled, parallel group, multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Corneal disorders

Interventions

Group one:

Deep anterior lamellar keratoplasty compared to penetrating keratoplasty.

Group two:

Posterior lamellar keratoplasty compared to penetrating keratoplasty.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Discard rate of donated corneas.

Key secondary outcome(s)

1. Visual acuity
2. Astigmatism
3. Stray light evaluation
4. Contrast sensitivity
5. Endothelial cell loss
6. Incidence endothelial rejection
7. Vision-related quality of life
8. Patient satisfaction

These will be measured before the operation, and at three, six and 12 months after the operation. A full economic evaluation will also be performed.

Completion date

01/01/2008

Eligibility**Key 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) less than 0.4
4. Patients who signed the informed consent

Posterior lamellar keratoplasty:

1. Endothelial dysfunction caused by pseudophakic or aphakic corneal oedema
2. (Fuchs) Endothelial dystrophy
3. BSCVA less than 0.4
4. Without severe scarring of the anterior stromal cornea
5. Patients who signed the informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not comply with the above inclusion criteria

Date of first enrolment

01/01/2005

Date of final enrolment

01/01/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Hospital Maastricht

Maastricht

Netherlands

6202 AZ

Sponsor information**Organisation**

University Hospital Maastricht (The Netherlands)

ROR

<https://ror.org/02d9ce178>

Funder(s)**Funder type**

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Funder Name

Dutch Association of the Blind and Partially Sighted (The Netherlands)

Funder Name

Netherlands Society for the Prevention of Blindness (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2011		Yes	No
Results article	results	01/10/2011		Yes	No
Other publications	economic evaluation	01/08/2012		Yes	No