ISRCTN02191620 https://doi.org/10.1186/ISRCTN02191620

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/02/2007	**Overall study status** Completed	
Last Edited 17/10/2012	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Discard rate of donated corneas.

Secondary outcome measures
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.

Overall study start date
01/01/2005

Completion date
01/01/2008

Eligibility

Key inclusion criteria
Deep anterior lamellar keratoplasty:
1. Keratoconus intolerant for contact lens wear, without previous hydrops or Descemets rupture
2. Stromal opacification not reaching Descemets 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

Age group
Adult

Sex
Both

Target number of participants
140

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
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6202 AZ

Sponsor information

Organisation
University Hospital Maastricht (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.unimaas.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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