# Influence of the donor-host interface on results of keratoplastic procedures currently in use in corneal surgery. A structured follow-up.

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The main objective is to establish whether a relationship can be demonstrated between the amount of light scattered at the post-operative corneal interface on the one hand and visual acuity and contrast sensitivity on the other. In addition, changes...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Ocular structural change, deposit and degeneration NEC |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON30230

**Source**
ToetsingOnline

**Brief title**
Structured follow-up of keratoplasty.

### Condition

- Ocular structural change, deposit and degeneration NEC

**Synonym**
corneal transplant

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam

**Source(s) of monetary or material Support:** Stichting Wetenschappelijk Onderzoek Oogziekenhuis - Prol. Dr. H. J. Flieringa.

## Intervention

**Keyword:** cornea, in vivo confocal microscope, lamellar keratoplasty

## Outcome measures

### Primary outcome

Quantification of possible relationship between corneal reflectivity (confocal

microscopy) and:

- visual acuity (logMAR)

- contrast sensitivity (Pelli Robson chart)

- keratoplastic technique

### Secondary outcome

Quantification of possible relationship between corneal reflectivity and:

- scatter measured by Oculus C-quant

- pachymetry (3 methods)

Quantification of:

- endothelial cell density

- quality of life

# Study description

### Background summary

The outcome of recently developed lamellar techniques of keratoplasty strongly depends on the optical properties of the donor-host interface. Thus far, no criteria are set for the optical quality of the post-operative cornea. Preferably, such an evaluation should be accurate, reliable and user-friendly at the same time. In vivo confocal microscopy appears to be meet these

requirements as a tool for inspection of the scatter properties of the corneal donor-host interface.

### Study objective

The main objective is to establish whether a relationship can be demonstrated between the amount of light scattered at the post-operative corneal interface on the one hand and visual acuity and contrast sensitivity on the other. In addition, changes over time will be explored for the parameters under examination.

### Study design

Prospective, non-randomized.

### Study burden and risks

Patients due for keratoplasty are standardly scheduled for one pre-op and six post-op visits. Study-related measurements will be performed during these visits and will take approximately 50 minutes extra time per session. Participants of this study do not benefit from the results of this study. Risks are negligible.

## Contacts

**Public**
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland
**Scientific**
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland

## Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Group 1, PKP:
- BCVA >= 0.4 (logMAR)
- not eligible for ALTK, DALK, PLK;Group 2, ALTK:
- BCVA >= 0.4 (logMAR);Group 3, DALK:
- BCVA >= 0.4 (logMAR)
- keratoconus without hydrops or Descemet*s rupture
- stromal opacities not reaching Descemet*s membrane
- no concommitant endothelial disease;Group 4, PLK:
- BCVA >= 0.4 (logMAR)
- endothelial dysfunction caused by pseudophakic or aphakic edema
- (Fuch*s) endothelial dystrophy

## Exclusion criteria

Group 1, PKP:
- mental retardation
- previous corneal surgery ;Group 2, ALTK:
- mental retardation
- history of (penetrating) keratoplasty
- HLA-typed keratoplasty;Group 3, DALK:
- mental retardation
- history of (penetrating) keratoplasty
- HLA-typed keratoplasty;Group 4, PLK:
- mental retardation
- history of (penetrating) keratoplasty
- HLA-typed keratoplasty
- severe scarring of anterior stroma

# Study design

## Design

**Study type:** Observational non invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 19-03-2007 |
| Enrollment: | 210 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 04-12-2006 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 |
| --- | --- |
| CCMO | NL14835.078.06 |