

A Randomized, Comparative Trial of Two *Mushroom* Keratoplasty Techniques in Keratoconus Patients. Femtosecond Laser Aided True Mushroom Keratoplasty versus Microkeratome Assisted Lamellar Keratoplasty (MALK).

Published: 17-02-2015

Last updated: 15-05-2024

To demonstrate that FS laser aided keratoplasty for KC is superior to MALK.

| | |
|------------------------------|--|
| Ethical review | Approved WMO |
| Status | Pending |
| Health condition type | Ocular structural change, deposit and degeneration NEC |
| Study type | Interventional |

Summary

ID

NL-OMON42181

Source

ToetsingOnline

Brief title

Femtosec Laser & MALK

Condition

- Ocular structural change, deposit and degeneration NEC

Synonym

keratoconus

Research involving

Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Astigmatism., Endothelial cell density., Keratoconus., Keratoplasty techniques.

Outcome measures

Primary outcome

Astigmatism.

Secondary outcome

Visus (BSCVA, UCVA, BclCVA).

Endothelial cell density.

Number of eyes that need a hard contactlens to achieve a VA > 0.5 at 1 year.

Graft survival.

RMS of Zernike polynomials of high order aberrations.

Contrast sensitivity and stray light.

Quality of vision questionnaire.

OT time and costs.

Study description

Background summary

With severe keratoconus (KC), refractive abnormalities become non-correctable and, eventually, a corneal transplant is the only treatment option left to restore vision. Continuing technological developments suggest that VA outcome and rehabilitation rate can be further improved. Surgical outcome, i.e. postoperative astigmatism, of femtosecond (FS) laser assisted mushroom keratoplasty and microkeratome assisted lamellar keratoplasty (MALK) will be

compared.

Study objective

To demonstrate that FS laser aided keratoplasty for KC is superior to MALK.

Study design

Randomized, comparative.

Intervention

FS laser aided keratoplasty or MALK.

Study burden and risks

The outcome of FS laser aided mushroom keratoplasty is expected to be better but the risk of endothelial complications is supposed to be higher. Assessments for this study are non-invasive and inconvenience is negligible. Extra time required for these measurements is approximately 1 hour per visit (5X).

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 \geq 18 years.

Informed consent.

Severe KC needing keratoplasty.

Exclusion criteria

Unable to attend the FU visits.

Mental retardation, including trisomy 21.

Severe progressive glaucoma.

History of retinal surgery, glaucoma surgery or age related macular disease.

Severe nystagmus.

History of surgical correction of astigmatism.

History of corneal or refractive surgery.

Study design

Design

| | |
|---------------------|-----------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Health services research |

Recruitment

NL

Recruitment status: Pending

| | |
|---------------------------|-------------|
| Start date (anticipated): | 01-04-2016 |
| Enrollment: | 38 |
| Type: | Anticipated |

Ethics review

| | |
|--------------------|---|
| Approved WMO | |
| Date: | 17-02-2015 |
| 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

ID: 22202
Source: NTR
Title:

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL51078.078.14 |
| OMON | NL-OMON22202 |