

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

No registrations found.

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

Summary

ID

NL-OMON22202

Source

Nationaal Trial Register

Health condition

KC patients indicated for keratoplasty.

Sponsors and support

Primary sponsor: The Rotterdam Eye Hospital

Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

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Astigmatism

Secondary outcome

- Astigmatism (subjective refraction) at 6 months.
- BSCVA, UCVA, BclCVA (LogMar) at 1, 3, 6, 12 months.
- Central endothelial cell density and morphology of the recipient pre-operatively
- Central endothelial cell density and morphology of the grafts preoperative, 6 and 12 months.
- Number of eyes that need a hard contactlens to achieve a VA > 0.5 at 1 year.
- Graft survival (in terms of clear grafts).
- RMS (root mean square) of Zernike polynomials of high order aberrations of the corneal surface (topography derived) at 1, 3, 6, 12 months.
- Contrast sensitivity (CS) and stray light at 1, 6 and 12 months.
- Quality of vision questionnaire at 1, 6 and 12 months.
- OT time and costs.

Study description

Background summary

Rationale: 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.

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

Study design: Randomized, comparative.

Study population: KC patients indicated for keratoplasty.

Intervention: FS laser aided keratoplasty or MALK.

Main study parameters/endpoints: Astigmatism.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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).

Study objective

Femtosecond (FS) laser aided keratoplasty for KC is superior to MALK.

Study design

baseline, 1, 3, 6, 12 month

Intervention

Femtosecond laser aided keratoplasty; MALK

Contacts

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Eligibility criteria

Inclusion criteria

- Age ≥ 18 years.
- Informed consent.
- Severe KC needing keratoplasty (i.e. high irregular astigmatism that cannot be corrected with daily wear hard contact lenses).

Exclusion criteria

- Unable to attend the FU visits.
- Mental retardation (including trisomy 21).
- Pregnancy/lactation (no pregnancy test required).
- Severe progressive glaucoma (stable glaucoma on topical therapy is excepted).
- History of retinal surgery, glaucoma surgery or age related macular disease.
- Severe nystagmus.
- History of surgical correction of astigmatism (including toric intra-ocular lens implants and phakic IOLs).
- 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

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-01-2015
Enrollment:	38
Type:	Anticipated

Ethics review

Positive opinion	
Date:	08-06-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42181
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5068
NTR-old	NTR5199
CCMO	NL51078.078.14
OMON	NL-OMON42181

Study results

Summary results

Not applicable