

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

Gepubliceerd: 08-06-2015 Laatste bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22202

Bron

Nationaal Trial Register

Aandoening

KC patients indicated for keratoplasty.

Ondersteuning

Primaire sponsor: The Rotterdam Eye Hospital

Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Astigmatism

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

baseline, 1, 3, 6, 12 month

Onderzoeksproduct en/of interventie

Femtosecond laser aided keratoplasty; MALK

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 intact).

- History of corneal or refractive surgery.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	38
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	08-06-2015

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42181

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

Not applicable