Standard versus transepithelial corneal crosslinking for treatment of progressive keratoconus

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To evaluate the role of the epithelium in the effect of CXL for treatment of progressive KC and to determine whether the epithelium should be removed or can be left intact during treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders congenital
Study type	Interventional

Summary

ID

NL-OMON39491

Source
ToetsingOnline

Brief title
Transepithelial corneal crosslinking

Condition

- Eye disorders congenital
- Ocular structural change, deposit and degeneration NEC

Synonym
corneal deformation, Keratoconus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Dr. F.P. Fischer Stichting;Utrecht en

Stichting Stichting Nederlands Oogheelkundig Onderzoek

Intervention

Keyword: Crosslinking, Epithelium, Keratoconus

Outcome measures

Primary outcome

The main study parameter is the keratometry outcome over a period of 1 year,

which is measured by corneal topography and Pentacam imaging.

Secondary outcome

The secondary objective is the incidence of epithelial healing problems after

treatment.

Study description

Background summary

The gold standard corneal crosslinking (CXL) technique involves the initial step of epithelial removal, in order to achieve a sufficient treatment effect (meaning: stabilisation of progressive keratoconus (KC). Our aim is to evaluate the effects of transepithelial CXL (TE-CXL), whereby the epithelium is left intact and the cornea is instead treated by a solution composed of 0.1% riboflavin, combined with enhancers, after which standard CXL is performed. This solution seems to facilitate riboflavin penetration into the corneal stroma through the intact epithelium. We expect to achieve a similar effect of TE-CXL with the advantage of a faster healing time and less risk of infections.

Study objective

To evaluate the role of the epithelium in the effect of CXL for treatment of progressive KC and to determine whether the epithelium should be removed or can be left intact during treatment.

Study design

Randomized clinical trial

Intervention

CXL is performed on all patients included in the study. Patients will be divided at random into two groups. Group 1 will undergo standard CXL treatment with the initial step of epithelial removal prior to application of riboflavin drops (3-minute intervals over a 30-minute period). Group 2 will undergo TE-CXL treatment, whereby the epithelium is left intact and alternate riboflavin drops will be applied (Ricrolin TE)

Study burden and risks

The treatment that will be investigated in this study consists of a semi-invasive procedure, whereby 2 components will be altered from the gold standard procedure. The gold standard CXL procedure involves the initial removal of the epithelium before riboflavin application. Studies in the literature state that the advantage of this initial step of epithelial removal is a better penetration of riboflavin solution through the corneal stroma. However, this initial step also poses the patient at a higher risk for post-CXL infections and epithelial healing problems. In contrast, the alternative TE-CXL procedures that will be investigated in this study are less invasive in nature, since they skip the initial step of epithelial removal. This could of benefit to the patient, since the risk of infection is believed to be less.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient age of >= 18 years, documented progressive KC (by Pentacam and/or corneal topography imaging), a clear central cornea, minimal corneal thickness of at the thinnest corneal location (Pentacam imaging), minimal Snellen corrected distance visual acuity of >= 0.4.

Exclusion criteria

Patient age less than 18 years, stable keratometry values over time, presence of corneal scar(s)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	30-05-2011
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-04-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-07-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL29961.041.10