Study Protocol

Title:

German Corneal Cross Linking Register

NCT-Number: NCT00560651

2026-04-23

Synopsis

1. Title

German Corneal Cross Linking **Register**

2. Project Manager

Prof. Dr. med. Suphi Taneri, FEBOS-CR

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3. Setting

Zentrum für Refraktive Chirurgie Münster

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4. Design

Prospective, Register

5. Participants

Patients diagnosed with keratokonus and treated with corneal cross Linking in Germany

2026-04-23

I. Responsibilities

Central Contact Person:

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Central Contact Backup:

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Overall Study Officials:

Study Chair Suphi Taneri , MD Augenklinik am St. Franziskus Hospital
Study Director Berthold Seitz , MD University of Homburg, Saar, Germany
Study Director Philip Maier , MD Univer. Freiburg, Germany
Study Director Claus Cursiefen , MD Univer. Erlangen, Germany
Principal Investigator Thomas Reinhard , MD Univers. Freiburg
Principal Investigator Arnd Heiligenhaus , MD Augenklinik am St.Franzsikus Hospital, Münster
Principal Investigator Walter Sekundo , MD Univers. Mainz
Principal Investigator Theo Seiler , MD IROC, Zürich
Principal Investigator Atilla Osvald , MD Univers Homurg, Saar
Principal Investigator Jan M Vetter , MD Univers. Mainz

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II. Background

Corneal Cross Linking is treatment modality for patients with keratoconus. A keratoconus is characterized by progressive bulging and thinning of the eye's cornea. Keratoconus is a potentially severely sight impairing condition that may necessitate corneal transplantation in the progressive state.

Corneal Cross Linking is designed to

- increase the cornea's mechanical stability
- to stop the progression of bulging and thinning of the cornea

- to prevent the need for corneal transplantation

Corneal Cross Linking is performed by

1. Applying Riboflavin (Vitamin B2) eye drops every 2 minutes for 30 minutes to the cornea
2. Illuminating the cornea with UV-light

III. Aim

This register of Corneal Cross Linking procedures performed in Germany serves to

- gather long-term results
- detect rare complications and side-effects
- evaluate the efficacy in a large number of patients

IV. Procedure

Apply Riboflavin 0.1% in Dextran 500 20% in NaCl solution

Illuminate with UV-light of 365 nm wave-length and 3.0 mW/cm² intensity at 5 cm distance

V. Eligibility Criteria

Inclusion Criteria:

- Patients diagnosed with keratoconus and treated with corneal cross Linking in Germany

Exclusion Criteria:

- Non-ectatic condition