

# A clinical pilot study to evaluate collagen cross-linking (CXL) as a treatment for bacterial keratitis

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| <b>Submission date</b><br>30/11/2009   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>22/01/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>30/10/2012       | <b>Condition category</b><br>Eye Diseases         | <input type="checkbox"/> Individual participant data  |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
LV 461:2008/67089

## Study information

**Scientific Title**  
To study the effect of collagen cross-linking (CXL) as a primary treatment for bacterial keratitis in two ophthalmological centres, through a non-randomised clinical pilot study of twenty patients

## **Study objectives**

Bacterial keratitis is a sight threatening condition with a relatively large risk for visual impairment. Bacterial strains are becoming increasingly resistant to all known antibiotics. In CXL a photo-activation of riboflavin is used, which is also used in Pathogen Inactivation Therapy in transfusion medicine. Several groups have presented treated ulcers and cases of infectious keratitis successfully treated with CXL. Based on these experiences a protocol to study CXL as a primary treatment for bacterial keratitis has been created.

## **Hypothesis:**

That CXL can be used as primary therapy for bacterial keratitis.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Regional Ethical Committee in Uppsala, Sweden, approved on the 6th October 2008 (ref: 2008 /250). An amendment was approved on the 5th June 2009.

## **Study design**

Prospective non-randomised clinical pilot study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Bacterial keratitis

## **Interventions**

Please note that as of 03/08/10 the status of this trial was changed to completed. The previously anticipated end date was 31/12/10. The decision was made to end the trial after the inclusion of 16 patients as study coordinators see this number as sufficient to answer the hypothesis.

Microbial culturing is conducted. CXL is performed with settings for keratoconus after pachymetry. Post-operatively the patient is examined one to several times daily until healing has taken place. Slit-lamp photography is done at each examination. The patient is excluded from the study if signs of infectious progress are seen and if the results from microbial culturing are negative. Healing of the keratitis at two consecutive visits is defined as the primary end-point. The patient is followed until no symptoms are present and complete healing of the ulcer has been observed.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Healing of the epithelium and arrest of corneal melting at two consecutive visits.

**Key secondary outcome(s)**

Any side effects and complications of treatment.

**Completion date**

31/07/2010

**Eligibility****Key inclusion criteria**

To be included in the study all patients must fulfil the following criteria:

1. Suspected bacterial keratitis
2. Aged 18 years or above, either sex
3. Signed informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Any antibiotic treatment for the current episode of keratitis
2. Suspicion of a non-bacterial keratitis
3. Pachymetry values under 400 mm
4. Pregnancy or breast-feeding
5. Allergy towards riboflavin or any substance in Ricrolin®
6. Participation in any ophthalmological study in which the follow-up is not completed
7. The patient might not be able to complete the follow-up after treatment required in the study

**Date of first enrolment**

20/03/2009

**Date of final enrolment**

31/07/2010

**Locations****Countries of recruitment**

Sweden

**Study participating centre**  
**Department of Ophthalmology**  
Örebro  
Sweden  
701 85

## Sponsor information

### Organisation

Clinical Research Support (CRS) Centre, Örebro (Sweden)

### ROR

<https://ror.org/02m62qy71>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Örebro University Hospital (Sweden) - Ophthalmological research funds (D-number: OLL-57221)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/01/2012   |            | Yes            | No              |