

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Non randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

Any side effects and complications of treatment.

Overall study start date

20/03/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20 (final recruitment: 16)

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)

Sponsor details

c/o Jes Mortensen, MD

Department of Ophthalmology

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Sponsor type

Research organisation

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article	results	01/01/2012		Yes	No