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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/01/2010	**Overall study status** Completed	
Last Edited 30/10/2012	**Condition category** Eye Diseases	

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
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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