

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluating the effect of UV-A/Riboflavin Collagen Cross-Linking in treatment of bacterial corneal ulcer

Protocol summary

Summary

- Purpose: the effect of collagen cross linking on treatment bacterial corneal ulcers - Study design: Randomized clinical trial single blind Inclusion Patient with moderate corned ulcer who admitted in khalili eye hospital - Exclusion criteria : all patient with other ocular or systemic diseases like rheumatologic disorders or corneal perforation - sample size: 32 patients All patients received standard treatment, half of them had Collagen Cross linkage as well on the time of admission - Time of intervention: at time of admission - The primary outcome : Evaluation of healing of corned ulcer

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101919581N1**
Registration date: **2015-01-23, 1393/11/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-23, 1393/11/03

Registrant information

Name

Shahram Bamdad

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 2830

Email address

shahrambamdad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of UV-A/Riboflavin Collagen Cross-Linking in treatment of bacterial corneal ulcer

Public title

Evaluating the effect of UV-A/Riboflavin Collagen Cross-Linking in treatment of bacterial corneal ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

32 patients with corneal ulcer will be selected 16 cases and 16 control group. The study will be restricted to patients who will refer to Khalili hospital; moderate corneal ulcers Patients that will have any kind of corneal perforation; those with a corneal descematocele; patients with collagen vascular disease and immunocompromised patients; and patients who will need any kind of emergency keratoplasty will be excluded from our study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Science - zand blvd

City

Shiraz

Postal code

7134814336

Approval date

2014-10-16, 1393/07/24

Ethics committee reference number

CT-P-9362-6212

Health conditions studied

1

Description of health condition studied

Corneal ulcers

ICD-10 code

H16.0

ICD-10 code description

Corneal ulcer

Primary outcomes

1

Description

Corneal ulcers

Timepoint

Before the intervention, and daily

Method of measurement

Response to treatment according to improvement of ulcer with measurement of epithelialization (millimeter) and improvement of stromal infiltration

Secondary outcomes

1

Description

Evaluation of non- healing corneal ulcers

Timepoint

Daily

Method of measurement

No improvement in corneal epithelialization and stromal infiltrations

Intervention groups

1

Description

We do collagen cross linkage at time of admission in case group . We instilled Riboflavin(1%) drop every five minute till 30 minute then ultraviolet radiation (400nm) for 30 minute and during this period riboflavin instilled every 5 minute. And we start fortified cefazolin (loomg/ml) and fortified gentamicin (14 mg/ml) every 30 minute and according to clinical response and result of culture and smear we change the therapy if needed

Category

Treatment - Surgery

2

Description

In controlled group we start fortified cefazolin (loomg/ml) and fortified gentamicin (14 mg/ml) every 30 minute and according to clinical response and result of culture and smear we change the therapy if needed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Shahram Bamdad

Street address

Khalili Street Shiraz Khalili Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

SAGE doctor Syed Hashmi

Street address

Shiraz University of Medical Sciences- zand blvd

City

Shiraz

Grant name

دانشگاه علوم پزشکی شیراز

Grant code / Reference number

92-01-01-6212

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Shahram Bamdad

Position

Corneal Fellowship

Other areas of specialty/work**Street address**

Shiraz University of Medical Sciences - zand blvd

City

Shiraz

Postal code

7134814336

Phone

+98 71 3230 5410

Fax

+98 71 3235 5936

Email

Shahrambamdad@yahoo.com

Web page address

Psorc.sums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences-

Full name of responsible person

Shahram Bamdad

Position

Corneal Fellowship

Other areas of specialty/work**Street address**

Shiraz University of Medical Sciences- zand blvd

City

Shiraz

Postal code

7134814336

Phone

+98 71 3230 5410

Fax

+98 71 3235 5936

Email

Shahrambamdad@yahoo.com

Web page address

Psorc.sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Shahram Bamdad

Position

Corneal Fellowship

Other areas of specialty/work**Street address**

Shiraz University of Medical Sciences - zand blvd

City

Shiraz

Postal code

7134814336

Phone

+98 71 3230 5410

Fax

+98 71 3235 5936

Email

Shahrambamdad@yahoo.com

Web page address

Psorc.sums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty