Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Excimer laser phototherapeutic keratectomy vs surgical keratectomy in treatment of post-burn persistent corneal epithelial defects with ulceration

Protocol summary

Summary

Persistent corneal defects (PCD) with superficial ulceration are often formed after severe ocular burns (grade IV). Such defects are recalcitrant to medicamental therapy and in some cases may lead to corneal perforation. Existing surgical methods of treatment (lamellar corneal grafting, amniotic membrane transplantation) always lead to dense corneal opacities and visual acuity loss. Results of surgical keratectomy (SK) in treatment of post-burn PCD in spite of years of application were never reported previously. Excimer laser phototherapeutic keratectomy (PTK) has been applied in treatment of a number of corneal pathologies (corneal dystrophies, scars, bullous keratopathy, recurrent erosions), but never - in treatment of post-burn PCD. The objective of the trial is to explore efficacy of excimer laser phototherapeutic keratectomy in treatment of post-burn persistent corneal defects with ulceration. Main inclusion criteria are presence of post-burn corneal epithelial defect with ulceration, non-decreased size of post-burn corneal defect during 10 days of conventional treatment. Main exclusion criteria are corneal defect of other than burn etiology, post-burn corneal defect with edge (edges) connected with the limbus and adjacent area of necrosis of perilimbal conjunctiva, deep post-burn corneal ulceration. The study population is all patients with severe ocular burns. Sample size is 20 patients. Intervention under study is excimer laser photherapeutic keratectomy. Main outcome measures are speed of corneal epithelialization, corneal epithelialization rate, visual acuity, recurrence rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710271555N1**
Registration date: **2009-02-01, 1387/11/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-02-01, 1387/11/13

Registrant information

Name

Oleksiy Buznyk

Name of organization / entity

The Filatov Institute of Eye Diseases and Tissue Therapy

Country

Ukraine

Phone

+380482636729

Email address

ojogi_glaz@te.net.ua

Recruitment status

Recruitment complete

Funding source

None

Expected recruitment start date

2009-02-01, 1387/11/13

Expected recruitment end date

2011-02-01, 1389/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Excimer laser phototherapeutic keratectomy vs surgical keratectomy in treatment of post-burn persistent corneal epithelial defects with ulceration

Public title
Excimer laser phototherapeutic keratectomy in treatment of post-burn persistent corneal ulcers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria - presence of post-burn corneal epithelial defect with ulceration, non-decreased size of post-burn corneal defect during 10 days of conventional treatment Exclusion criteria - corneal defect of other than burn etiology, post-burn corneal defect with edge(edges) connected with the limbus and adjacent area of necrosis of perilimbal conjunctiva, deep post-burn corneal ulceration
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
In the main group (phototherapeutic keratectomy) all patients, which will fit the inclusion criteria mentioned above, will be included prospectively. In the control group (surgical keratectomy) patients, which will fit the inclusion criteria mentioned above, will be included retrospectively on the basis of case histories analysis

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee
Name of ethics committee
The Bioethics Committee of the Filatov Institute of Eye Diseases and Tissue Therapy
Street address
Frantsuzkyi bulvar 49/51
City
Odessa
Postal code
65061
Approval date
2008-11-07, 1387/08/17
Ethics committee reference number
11

Health conditions studied

1

Description of health condition studied
post-burn corneal defect with ulceration
ICD-10 code
H 16.0
ICD-10 code description
Corneal ulcer

Primary outcomes

1

Description
Speed of corneal epithelialization
Timepoint
6 months
Method of measurement
Number of days after operation which was necessary to get corneal epithelialization. Corneal epithelialization it is absence of corneal staining after fluorescein test.

2

Description
Corneal epithelialization rate
Timepoint
6 months
Method of measurement
Ratio of number of successful corneal epithelializations to number of operations

Secondary outcomes

1

Description
Visual acuity
Timepoint
6 months
Method of measurement
Golovin-Sivtsev chart for measurement of visual acuity

2

Description
Recurrence rate

Timepoint
6 months
Method of measurement
Ratio of number of corneal defect recurrences to number of successful corneal epithelializations

Intervention groups

1

Description
excimer laser phototherapeutic keratectomy
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The Filatov Institute of Eye Diseases and Tissue Therapy
Full name of responsible person
Mr Oleksiy Buznyk
Street address
Frantsuzkyi bulvar 49/51
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The Filatov Institute of Eye Diseases and Tissue Therapy
Full name of responsible person
Mr Stanislav Iakymenko
Street address
Frantsuzkyi bulvar 49/51
City
Odessa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The Filatov Institute of Eye Diseases and Tissue Therapy
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
The Filatov Institute of Eye Diseases and Tissue Therapy
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Person responsible for updating data

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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