

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 medicamentous 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 phototherapeutic 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

City

Odessa

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

Full name of responsible person

Mr Oleksiy Buznyk

Position

Doctor-ophthalmologist / M.D.

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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