

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of mitomycine C on DCR (Dacryosystorhinostomy) with endonasal endoscopic guidance in lacrimal duct stenosis referring to medical center affiliated to Kashan university of medical sciences

Protocol summary

Summary

Effect of Mitomycine C on DCR (Dacryosystorhinostomy) with endonasal endoscopic guidance examine in a double blind accidental survey. Patients with lacrimal duct stenosis referring to medical centers affiliated to Kashan university of medical sciences who aged 35-65 years old and tearing along with (Recurrent acute dacryocystitis, increase in lacrimal minisc, have a reflux when the pressure on the lacrimal sac, Confirmed the diagnosis of nasolacrimal lavage selected. Patient with history: tearing at birth, trauma to face and nose, Nasal and sinus surgery, Mucosal lacrimal sac, canalicole obstruction, Coagulation disorders, hemophilia, other external nasal disease, lacrimal sac neoplasm, Corneal ulcers or foreign body on cornea, abnormality in ponctum position are excluded from study. Sample size 92 patients calculate (46 for each group). During surgery sponge impregnated with 0.02 percent mitomycin C use in osteotomy site for five minutes and then Washed with 50 cc normal saline and clean with endonasal endoscopic guidance. For control group use placebo instead of Mitomycine C. epiphoria follow.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010816136N1**
Registration date: **2014-05-18, 1393/02/28**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-18, 1393/02/28

Registrant information

Name

Fatemeh Rangraz Jeddi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 8883

Email address

rangrazejeddi_f@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of mitomycine C on DCR (Dacryosystorhinostomy) with endonasal endoscopic guidance in lacrimal duct stenosis referring to medical center affiliated to Kashan university of medical sciences

Public title

Effect of mitomycine C on DCR (Dacryosystorhinostomy)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 35-65 years old and tearing along with (Recurrent acute dacryocystitis);

increase in lacrimal minisc; have a reflux when the pressure on the lacrimal sac; confirmed the diagnosis of nasolacrimal lavage selected. Patient with history of tearing at birth, trauma to face and nose, nasal and sinus surgery, mucosal lacrimal sac, canalicule obstruction, coagulation disorders, hemophilia, other external nasal disease, lacrimal sac neoplasm, corneal ulcers or foreign body on cornea, abnormality in ponctum position are excluded from study.

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Ravand avenue

City

Kashan

Postal code**Approval date**

2013-08-13, 1392/05/22

Ethics committee reference number

29/5/1/1869

Health conditions studied**1****Description of health condition studied**

Stenosis of lacrimal passages

ICD-10 code

H04.5

ICD-10 code description

Stenosis and insufficiency of lacrimal passages

Primary outcomes**1****Description**

Tearing

Timepoint

One week, one month, six months after surgery

Method of measurement

yes/no

Secondary outcomes**1****Description**

Tearing reflex

Timepoint

One day, one week, one month and six months

Method of measurement

no/ purulent/ aqueous

Intervention groups**1****Description**

During surgery sponge impregnated with 0.02 percent mitomycin C use in osteotomy site for five minutes and then Wash with 50 cc normal saline and clean with endonasal endoscopic guidance.

Category

Treatment - Drugs

2**Description**

For control group Dacryosystorhinostomy under general anesthesia is routinely performed with placebo instead of Mitomycine C

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Medical centers affiliated to Kashan University of Medical Sciences

Full name of responsible person**Street address****City**

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Hamidi

Street address

Kashan University of Medical Sciences, research deputy- Ravand avenue

City

Kashan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Rangraz Jeddi

Position

Faculty member

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

Kashan University of Medical Sciences, Ravand avenue

City

Kashan

Postal code**Phone**

+98 36 1555 0021

Fax

+98 36 1555 8883

Email

angrazejeddi_f@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Mehdi Shaeri

Position

Ophtalmologist

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

Kashan University of Medical Sciences, Ravand avenue

City

Kashan

Postal code**Phone**

+98 36 1555 0021

Fax**Email**

shaeri_m@kaums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Rangraz Jeddi

Position

PhD of Health Information Management

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

Kashan University of Medical Sciences, Ravand avenue

City

Kashan

Postal code**Phone**

+98 36 1555 8883

Fax**Email****Web page address**

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