

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Efficacy of probing accompanied by mitomycin-c for treatment of complete, primery nasolacrimal duct obstruction in adults in Jahrom Mottahari hospital between 1386-88

Protocol summary

Summary

The objective of this study is to determine the efficacy of probing with adjunctive mitomycin-c (MMC) in adults with nasolacrimal duct obstruction (NLDO). This is a randomized, double-blind, placebo controlled trial study. The study population comprised adults with nasolacrimal duct obstruction. We will include men and women adult patients aged 18 or more with chief complaint of epiphora and will exclude those with lacrimal duct anomalies. Sample size will be 140 patients whom will divide into two groups (each one with 70 patients). Case group will receive 0.2 mg/ml mitomycin-c and controls will receive normal saline as placebo. Patients will be followed up 9 months. Patients' post probing epiphora was evaluated at 2 weeks, 1, 3, 6 and 9 months postoperatively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040310241N1**

Registration date: **2013-04-11, 1392/01/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-04-11, 1392/01/22

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Jahrom University of Medical Sciences

Expected recruitment start date

2008-04-03, 1387/01/15

Expected recruitment end date

2009-12-03, 1388/09/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of probing accompanied by mitomycin-c for treatment of complete, primery nasolacrimal duct obstruction in adults in Jahrom Mottahari hospital between 1386-88

Public title

Efficacy of probing with mitomycin-c in treatment of nasolacrimal duct obstruction.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Adults aged 18 or more. 2. Both sexes of men and women. 3. Patients with chief complaint of epiphora. Exclusion criteria: 1. Eye trauma. 2. Nasal structure abnormalities. 3. lacrimal system tumors.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **140****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**

Jahrom University of Medical Sciences

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Research department, Jahrom University of Medical Sciences, Motahari avenue, Jahrom, Fars, Iran

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Postal code

193

Approval date

2007-07-31, 1386/05/09

Ethics committee reference number

5016/دآ

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

Nasolacrimal duct obstruction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Amount of epiphora

Timepoint

Two weeks, 1, 3, 6, and 9 months post intervention.

Method of measurement

Observational

Secondary outcomes

empty

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

0.2 mg/ml mitomycin-c during nasolacrimal probing

Category

Treatment - Drugs

2**Description**

Normal saline during nasolacrimal probing

Category

Placebo

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

Motahari hospital

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

Jahrom

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Dr Kavous Solhjoui

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Research department, Jahrom University of medical Sciences, Jahrom, Fars, Iran

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

Yes

Title of funding source

Jahrom 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

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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