

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Monocanalicular versus Bicanalicular Silicon Tube Intubation for Nasolacrimal Duct Stenosis in Adults

Protocol summary

Summary

The purpose of this study is compare the succses rate of monocanalicular versus bicanalicular intubation of nasolacrimal duct for nasolacrimal duct stenosis in adult. The patients with nasolacrimal duct stenosis and water entranse into troat + water reflux from other panctum in irrigation test are included in this study. The patients with privious lacrimal surgery, privious lacrimal trauma, sinus disease, punctal or lid disease, ocular surface disease, removal of silicon stent before 3 months, follow up <3 months are excluded. In a prospective randomized clinical trial, 56 eyes with nasolacrimal duct stenosis undergo either monocanalicular silicone intubation (35 eyes) or bicanalicular silicone intubation (35 eyes).Tube removal was planned for 3 months postoperatively. Treatment success was defined abcence of epiphora at 3 months after tube removal.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102234580N1**

Registration date: **2011-04-13, 1390/01/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-04-13, 1390/01/24

Registrant information

Name

Dima Andalib

Name of organization / entity

Nikookary eye hospital, Tabriz Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1655 1332

Email address

andalibd@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences

Expected recruitment start date

2010-10-29, 1389/08/07

Expected recruitment end date

2012-03-10, 1390/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Monocanalicular versus Bicanalicular Silicon Tube Intubation for Nasolacrimal Duct Stenosis in Adults

Public title

Monocanalicular versus Bicanalicular Silicon Tube Intubation for Nasolacrimal Duct Stenosis in Adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.epiphora 2.water entranse into troat + water reflux from other panctum in irrigation test 3.DDT test> 5 minutes 3.NLD obstruction in scintigraphy. Exclusion criteria: 1.privious lacrimal surgery 2.privious lacrimal trauma 3.sinus disease 4.punctal or lid disease 5.ocular surface disease 6.removal of silicon stent before 3 months 7.follow up <3 months.

Age

From **14 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 28

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz university of medical sciences

Street address

Tabriz university of medical sciences

City

Tabriz

Postal code**Approval date**

2010-09-27, 1389/07/05

Ethics committee reference number

5/4/4867

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

Nasolacrimal duct stenosis

ICD-10 code

H04.5

ICD-10 code description

Stenosis and insufficiency of lacrimal passages

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

Absence of epiphora

Timepoint

3 months after tube removal

Method of measurement

DDT test

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

complication

Timepoint

3 months after tube removal

Method of measurement

examination

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

group 1: monoanalicular silicon intubation

Category

Treatment - Surgery

2**Description**

Group2: bicanalicular silicon tube intubation

Category

Treatment - Surgery

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

Nikookary Eye Hospital

Full name of responsible person

Dr. Dima Andalib

Street address

Abbasi st.

City

Tabriz

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

Tabriz university of medical sciences

Full name of responsible person

Vice chancellor for research

Street address

Tabriz university of medical sciences

City

Tabriz

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

Yes

Title of funding source

Tabriz 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

Nikookary hospital

Full name of responsible person

Dr. Dima Andalib

Position

Assistant professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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