

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of outcome following Dacryocystorhinostomy with or without silicon stent appliance; a randomized clinical trial

Protocol summary

Summary

The present study aims to evaluate the effect of silicone stent appliance in DCR through comparing it with conventional DCR. A target population of 50 patients is considered for this study. In this randomized clinical trial Patients with Nasolacrimal duct obstruction attending to Otolaryngology clinic of Baqiyatallah hospital will be assessed for eligibility. After confirmation of diagnosis by history taking, physical examination and Dacryocystography and signing a written informed consent form, patients will be randomly allocated to two groups regardless of age, gender and disease duration; group A patients will undergo endoscopic Dacryocystorhinostomy (DCR) with silicon stent and group B patients will undergo conventional endoscopic Dacryocystorhinostomy. Silicon stent will be removed one month after intervention. Etiology of disease and method of surgery will be explained for patients prior to intervention. Patients with previous DCR, Previous history of nasolacrimal duct surgery, not willing to participate in the study or concurrent sinus disease will be excluded from the study. Demographic and main complaints of patients will be recorded in a pre designed checklist. Patients in both groups will be evaluated for symptom resolution, peri and post operational complications such as bleeding, discharge, adhesion and punctuate granuloma formation in first and sixth months after intervention. In every visit patients will undergo diagnostic endoscopy in terms of obstruction evaluation and results will be recorded for each patient separately.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101717413N18**

Registration date: **2016-10-24, 1395/08/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-24, 1395/08/03

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of Research in Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcome following Dacryocystorhinostomy with or without silicon stent appliance; a randomized clinical trial

Public title

Evaluating the effect of silicone stent application in

Endoscopic Dacryocystorhinostomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Obstructive Etiology of Nasolacrimal duct
Exclusion Criteria: Previous history of nasolacrimal duct surgery; Previous history of dacryocystorhinostomy; Not willing to participate

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 50

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

Baqiyatallah University of Medical Sciences

Street address

Nosrati Alley, Sheykh Bahaei Street, Mollasadra street, Vanaq Square, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-04-21, 1393/02/01

Ethics committee reference number

IR.BMSU.REC.1393.31

Health conditions studied

1

Description of health condition studied

Nasolacrimal Duct Obstruction

ICD-10 code

H04.5

ICD-10 code description

Stenosis and insufficiency of lacrimal passages

Primary outcomes

1

Description

Epiphora

Timepoint

first and sixth month after intervention

Method of measurement

History and Physical Examination

Secondary outcomes

1

Description

Duct Adhesion

Timepoint

First and Sixth Months after intervention

Method of measurement

Endoscopy

2

Description

Punctate granuloma

Timepoint

First and Sixth Months after intervention

Method of measurement

Endoscopy

Intervention groups

1

Description

Patients in intervention group will undergo endoscopic Dacryocystorhinostomy (DCR) with silicon stent application.

Category

Treatment - Surgery

2

Description

Patients in control group will undergo conventional endoscopic Dacryocystorhinostomy (without stent application)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Mohammad Hossein Khosravi

Street address

Baqiyatallah Hospital, Mollasadra st., Vanaq sq.,
Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Morteza Izadi

Street address

Baqiyatallah University of Medical Sciences, Nosrati
Alley, Sheykh Bahaei st., Mollasadra st., Vanaq sq.,
Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Baqiyatallah 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

Student Research Committee, Baqiyatallah University
of Medical Sciences, Tehran, Iran

Full name of responsible person

Mohammad Hossein Khosravi

Position

Secretary General

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Otorhinolaryngology, Head and Neck
Surgery, Faculty of Medicine, Baqiyatallah Universi

Full name of responsible person

Masoumeh Saeedi

Position

Otolaryngologist

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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