Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the modified surgical interventions with Probing, Turbinate fracture and Crowforded in treatment of congenital obstruction of nasolacrimal duct: a Randomized controlled clinical trial

Protocol summary

Study aim

Comparison of success rate in modified surgical intervention methods with probing method with turbine fracture and Crawford implantation in the treatment of congenital nasolacrimal duct obstruction

Design

4 arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

This study will evaluate 4 surgical treatments for the treatment of congenital obstruction of the pure nasolacrimal duct in children under 5 years of age at Farabi hospital. Patients will be examined and examined 4 times after entering the study, and finally, within 6 months after the treatment intervention, they will undergo a complete clinical examination and fluorescein test. The results of this test will be reported positively or negatively, so that the positive result of this test is equal to the openness of the duct and its negative is equivalent to the obstruction of the duct.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children under 5 years of age in whom the diagnosis of congenital nasolacrimal duct obstruction is definitive Conditions of non-entry: having accompanying disorders in facial ossification, cleft palate (even hidden), developmental disorders or defects

Intervention groups

Patients underwent one of 4 different surgical intervention methods in the treatment of congenital nasolacrimal duct obstruction: Nasolacrimal duct probing surgical intervention with lower nasal turbine rupture And nasolacrimal duct probing surgery with Crawford implantation By nasolacrimal duct probing surgery as a basic method And nasolacrimal duct probing surgery with lower nasal turbine rupture and Crawford implantation as the gold standard method

Main outcome variables

Determining the appropriate surgical intervention method with the least invasiveness and the best effectiveness in the treatment of congenital nasolacrimal duct obstruction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220120053771N1**
Registration date: **2022-02-08, 1400/11/19**
Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**
Update count: **0**

Registration date

2022-02-08, 1400/11/19

Registrant information

Name

Sahel Soltani Shahgoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 1080

Email address

sahelsoltan93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the modified surgical interventions with Probing, Turbinate fracture and Crowforded in treatment of congenital obstruction of nasolacrimal duct: a Randomized controlled clinical trial

Public title

Success rate in the treatment of congenital nasolacrimal duct obstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

pure type of congenital nasolacrimal duct obstruction, Age under 5 years, negative fluorosin test without underlying disease or other syndromic disorder, without previous history of nasolacrimal duct intervention or manipulation.

Exclusion criteria:

Patient / parent dissatisfaction with the study, uncontrollable infection, underlying disease or limitation of anesthesia, concomitant tumors or bleeding disorders, concomitant disorders of facial ossification, cleft palate (even (Secretly), developmental disorders or defects, problems related to the pituitary gland or Ratke sinus and other abnormalities of the midline of the face.

Age

To **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the patients with the ability to enter the study, a three-digit code will be assigned to each patient, which will introduce the patient in all stages of the study and replace his name and other identity details. Then, a data collection form will be completed for patients and written informed consent will be obtained. In the next stage, patients will be divided into one of 4 intervention groups based on the principles of randomization and blinding and using block randomization method. Patients and evaluators will be unaware of the type of intervention performed during the study and the principles of dual blindness will be observed. Randomization will be based on a predetermined list. May 164 patients will be divided into 4 groups based on sex blocks. The desired list will be prepared by Randlist software.

Blinding (investigator's opinion)

Double blinded

Blinding description

After determining the patients with the ability to enter the study, a three-digit code will be assigned to each patient, which will introduce the patient in all stages of the study and replace his name and other identity details. Patients and evaluators will be unaware of the type of intervention performed during the study and the principles of dual blindness will be observed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran university of medical sciences, Pour sina Ave, keshavarz Blv, Tehran

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2022-03-01, 1400/12/10

Ethics committee reference number

00000000

Health conditions studied

1

Description of health condition studied

Congenital obstruction of the nasolacrimal duct

ICD-10 code

H04.53

ICD-10 code description

Neonatal obstruction of nasolacrimal duct

Primary outcomes

1

Description

Comparison of success rate in modified surgical intervention methods with probing method with turbine

fracture and Crawford implantation in the treatment of congenital nasolacrimal duct obstruction

Timepoint

patients will be examined for the success of the intervention as well as the complications of the interventionm, a day after the intervention,. At 3 months and 6 months after the surgery, patients will be re-evaluated for the visual system and fluorocin test will be performed, and the results of follow-up and examination at times 0, 3 and 6 (months) will be evaluated and compared.

Method of measurement

At each follow-up, patients will undergo a complete evaluation of the visual system and perform a fluorescein test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Nasolacrimal duct probing surgery with rupture of the lower nasal turbine

Category

Treatment - Surgery

2

Description

Intervention group: Nasolacrimal duct probing surgery with Crawford implantation

Category

Treatment - Surgery

3

Description

Intervention group: Nasolacrimal duct probing surgery as a basic procedure

Category

Treatment - Surgery

4

Description

Intervention group: Nasolacrimal duct probing surgery with lower nasal turbine fracture and Crawford implantation as the gold standard method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

Sahel Soltani Shahgoli

Street address

Farabi hospital, South Kargar Ave, Qazvin Sqr

City

Tehran

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1336616351

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sahelsoltan93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sahel Soltani Shahgoli

Position

Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
After the end of the study, the results of the study of the consequences and data analysis will be published in the form of an article with details and working methods.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
After printing the results, everyone will have access to the documents
Under which criteria data/document could be used
After printing the results, everyone will have access to the documents
From where data/document is obtainable
By sending an email to the responsible author
What processes are involved for a request to access data/document
By sending an email to the responsible author
Comments