

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The evaluation of the effect of intravenous Tranexamic acid in reducing the amount of bleeding during external DCR (Dacryocystorhinostomy) in patients with nasolacrimal duct obstruction (NLDO) compared to control group

Protocol summary

Study aim

Reduction of bleeding during external dacryocystorhinostomy(DCR)

Design

Clinical trial with control group, double-blind, randomized, phase 3 on 70 patients, pass software was used for randomization.

Settings and conduct

This study is performed on patients with nasolacrimal duct obstruction. The surgery is performed by a single skilled surgeon in Khatam Al-Anbia Ophthalmology Hospital in Mashhad. The study is double blind. The researcher and evaluator will be blinded in this study. The method of blinding is that the evaluator and researcher are unaware of the patients in the intervention and control groups.

Participants/Inclusion and exclusion criteria

Patients with nasolacrimal duct obstruction(NLDO) who don't have a history of coagulation disorders; Covid-19 infection and trauma to the lacrimal drainage system are included in the study.

Intervention groups

In the intervention group, 10 mg per kg intravenous tranexamic acid will be injected, 30 minutes before surgery. In the control group, surgery will be performed without placebo.

Main outcome variables

the amount of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211121053138N1**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

samaneh gholamhoseinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3844 0459

Email address

gholamhoseinpoursamaneh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-21, 1400/09/30

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of intravenous Tranexamic acid in reducing the amount of bleeding during external DCR (Dacryocystorhinostomy) in patients with nasolacrimal duct obstruction (NLDO) compared to

control group

Public title
The evaluation of the effect of intravenous Tranexamic acid in external DCR (Dacryocystorhinostomy)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with nasolacrimal duct obstruction
Exclusion criteria:
Any history of trauma to lacrimal drainage system
History of coagulopathy state History of bleeding disorders History of Covid-19 in the last 6 months

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of the structure will be performed using the sequence generated by PASS statistical software. The generated sequences are placed in closed envelopes in order so that their contents are not visible from the outside and an envelope will be allocated for each patient who agrees to participate in the project, respectively. Eventually the patient will be randomly placed in the control or intervention group

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be double blind. Impact assessor will be blinded to type intervention and the researcher who must enter the data into the checklist will be blinded to the type of intervention

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-
Mashhad University of Medical Sciences

Street address
No. 53 Beheeshti Ave, Kohsangi Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9175914785

Approval date
2021-11-01, 1400/08/10

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.520

Health conditions studied

1

Description of health condition studied

nasolacrimal duct obstruction

ICD-10 code

H0405

ICD-10 code description

Stenosis and insufficiency of lacrimal passages

Primary outcomes

1

Description

Record the amount of intraoperative bleeding at external dacryocystorhinostomy

Timepoint

at the end of surgery

Method of measurement

The amount of bleeding recorded by a standard suction device in a calibrated tank.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tranexamic acid will be injected intravenously only once, at a dose of 10 mg per kilo, half an hour before surgery. The manufacturer of the drug is CASPIAN TAMIN

Category

Treatment - Drugs

2

Description

Control group: no placebo will be injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-Al-Anbia hospital

Full name of responsible person

Samaneh Gholamhosseinpour-Omran

Street address

No.41 Gharani Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9175914785

Phone

+98 51 3728 1400

Email

gholamhoseinpoursamaneh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Maliheh Dadgar Moghadam

Street address

No. 41 Gharani

City

Mashhad

Province

Razavi Khorasan

Postal code

9175914785

Phone

+98 51 3841 2081

Email

dadgarmoghaddamm@mums.ac.ir

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Samaneh Gholamhosseinpour-Omran

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

No. 53 Beheshti Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9175914785

Phone

+98 51 3844 0459

Email

gholamhoseinpoursamaneh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Samaneh Gholamhosseinpour-Omran

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

Street address

No. 53 Beheshti Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9175914785

Phone

+98 51 3844 0459

Email

gholamhoseinpoursamaneh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Samaneh Gholamhosseinpour-Omran

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

Street address

No. 53 Beheshti 53 Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9175914785

Phone

+98 51 3844 0459

Email

gholamhoseinpoursamaneh@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available