Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

The evaluation of the effect of intravenous Tranexamic acid in reducing the amount of bleeding during external DCR (Dacryocyctorhinostomy) 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
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Name of organization / entity
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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 (Dacryocyctorhinostomy) 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 (Dacryocyctorhinostomy)
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
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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 insufficientcy of lacrimal passages

Primary outcomes

1

Description
Record the amount of intraoperative bleeding at external dacryocyctorhinostomy
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
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No.41 Gharani Ave
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Maliheh Dadgar Moghadam
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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
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
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Resident
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Person responsible for updating data

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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