

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of local tranexamic acid on reducing of intra and post external dacryocystorhinostomy hemorrhage in patients with primary acquired nasolacrimal duct abstruption

#### Protocol summary

Reduce the amount of bleeding during surgery

#### Study aim

Determine the Effectiveness of Local Tranexamic Acid on Reducing of intra and post external Dacryosystorhinosity hemorrhage in Patients with Primary Acquired Obstruction of Nasolacrimal Duct

#### Design

Phase 3 clinical trial, double-blind randomized, control group, parallel groups, sample size 126, randomization of quadruple computer blocks

#### Settings and conduct

This study will be conducted at the Amiralmomenin Medical Center of Rasht. After obtaining informed consent from patients, four groups of randomized blocks will be studied in two intervention and control groups. After the patient is ready for surgery, the desired solution and placebo are injected in the surgical site (0.5 ml in the posterior region, 0.5 ml in the superior and in the inferior, and 0.5 ml in the infra orbital nerve). The bleeding from the surgical site by suction blood volume assessment and surgeon satisfaction of the surgical field numerically 1: good, 2: moderate and 3: Bad evaluated in two groups.

#### Participants/Inclusion and exclusion criteria

Entry requirements: patients over 50 years of age with primary and acquired obstruction of the nasolacrimal duct of the candidate for surgery dacryosisturinostomy (DCR). Non-arrival conditions: any disturbances in coagulation tests.

#### Intervention groups

In the intervention group, the following combination is injected at the surgical site: 3.5 ml Bupivaine 5%, 4 ml Lidocain 2%, 0.1 Adrenalin 1/100000, 2.5 ml Tranexamic Acid In the control group, the following combination is injected at the surgical site: 3.5ml Bupivaine 5%, 4ml Lidocain 2% , 0.1 Adrenalin 1/100000, Normal saline 0.05 ml/kg

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140310016917N6**

Registration date: **2018-10-16, 1397/07/24**

Registration timing: **retrospective**

Last update: **2018-10-16, 1397/07/24**

Update count: **0**

##### Registration date

2018-10-16, 1397/07/24

##### Registrant information

##### Name

Ali Ashraf

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1321 0434

##### Email address

aliashraf@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-06, 1397/06/15

##### Expected recruitment end date

2018-09-21, 1397/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**

The effects of local tranexamic acid on reducing of intra and post external dacryocystorhinostomy hemorrhage in patients with primary acquired nasolacrimal duct abstruction

**Public title**

The effects of local tranexamic acid on dacryocystorhinostomy hemorrhage

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with primary and acquired obstruction of the nasolacrimal duct undergo surgery for dacryosisturinostomy under local anesthesia

**Exclusion criteria:**

Coagulation disorders Age less than 50 years Surgery with general anesthesia Allergic reaction to lidocaine or tranexamic acid Uncontrolled hypertension History of anticoagulation History of thromboembolic disease and thrombophilia Hemoglobin is less than 10

**Age**

From **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **126**

Actual sample size reached: **126**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Quadruple random blocks using statistical software

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participant: the patient is unaware of the type of local drug combination. Clinical care: the person administering the drug is unaware of the presence of tranexamic acid. Evaluation of outcomes: the type of drug combination is not known and only measures the amount of bleeding.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Guilan university of Medical Sciences

**Street address**

Namjoo street

**City**

Rasht

**Province**

Guilan

**Postal code**

4193893345

**Approval date**

2018-09-22, 1397/06/31

**Ethics committee reference number**

IR.GUMS.REC.1397.242

**Health conditions studied**

1

**Description of health condition studied**

Congenital and secondary stenosis and stricture of lacrimal duct

**ICD-10 code**

Q10.5

**ICD-10 code description**

Congenital stenosis and stricture of lacrimal duct

**Primary outcomes**

1

**Description**

Reduced bleeding during surgery

**Timepoint**

During and after the surgery

**Method of measurement**

Suctioned blood volume and quality of the surgical field surgeon

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: 3.5ml Bupicaine 5%, 4ml Lidocain 2%, 0.1ml Aderenalin 1/100000,2.5ml Tranexamic Acid

**Category**

Treatment - Drugs

2

**Description**

Control group: 3.5ml Bupicaine 5%, 4ml Lidocain 2%,  
0.1ml Aderenalin 1/100000, Normal salin 0.05 ml/kg

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Amiralmoemenin hospital

**Full name of responsible person**

Ali Ashraf

**Street address**

Dr. Heshmati Square., Shahrivar St.

**City**

Rasht

**Province**

Guilan

**Postal code**

41937-13194

**Phone**

+98 13 3323 6886

**Fax**

+98 13 3323 6886

**Email**

crdu.Poursina@gums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Shadman Nemati

**Street address**

Namjoo street, shahid siyadati street

**City**

Rasht

**Province**

Guilan

**Postal code**

41937-13194

**Phone**

+98 13 3333 6394

**Fax**

+98 13 3333 6395

**Email**

research@gums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Rasht 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**

Rasht University of Medical Sciences

**Full name of responsible person**

Ali Ashraf

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Prastar street

**City**

Rasht

**Province**

Guilan

**Postal code**

41937-13194

**Phone**

+98 13 3332 2250

**Fax**

**Email**

alishraf@gums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Ali Ashraf

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Parastar street

**City**

Rasht

**Province**

Guilan

**Postal code**

41937-13194

**Phone**

+98 13 3332 2250

**Email**

alishraf@gums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Ali Ashraf

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Parastar street

**City**

Rasht

**Province**

Guilan

**Postal code**

41937-13194

**Phone**

+98 13 3332 2250

**Email**

aliashraf@gums.ac.ir

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

It will be published as a scientific article

**When the data will become available and for how long**

A year after the publication of the article

**To whom data/document is available**

Researchers working in academia and academia

**Under which criteria data/document could be used**

There is no item

**From where data/document is obtainable**

aliashraf@gums.ac.ir

**What processes are involved for a request to access data/document**

aliashraf@gums.ac.ir

**Comments**