

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### An investigation of the topical impact of lemon juice on impulse control of spontaneous nasal bleeding in patients referred to the Emergency Services

#### Protocol summary

##### Study aim

Evaluation of the effect of lemon juice in control of spontaneous nasal bleeding

##### Design

A parallel randomized double-blind controlled clinical trial, will be performed on patients referred to the emergency ward with a diagnosis of spontaneous nasal bleeding. 150 patients will be randomly assigned to receive the intervention and the placebo using a random number table .

##### Settings and conduct

150 patients with spontaneous nasal bleeding referring to emergency ward of Rahnemoun Hospital, Yazd, after receiving an informed consent, will be assigned randomly to the A and B groups. The bottles of cottons containing lemon juice (5 drops) (intervention) or phenylephrine (placebo) will be separated by A and B labels by someone irrelevant to the study (participants and researchers will be blinded to the type of treatment). After putting lemon juice or placebo cottons in the patient's nose, nasal bleeding will be checked after 5 and 10 minutes. Patients will be followed for the next 24 hours for control of bleeding. In case of non-recovery within 10 minutes of either A or B intervention, standard therapy (anterior tampon) will be applied. The results of 2 groups will be compared together.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women referred to the emergency ward of Shahid Rahnemoun Hospital, Yazd with a diagnosis of spontaneous nasal bleeding, age range of 18-55 years who wish to participate in the study. Exclusion criteria: Pregnancy and underlying liver, kidney and heart disease, hereditary or acquired coagulopathy and a history of lemon or phenylephrine or lidocaine sensitivity and trauma.

##### Intervention groups

Intervention: Putting cotton containing 2% lidocaine and

lemon juice (5 drops) in the patient's nose Control:

Putting cotton containing 2% lidocaine and phenylephrine in the patient's nose

##### Main outcome variables

Nasal bleeding after 5, 10 minutes and 24 hours

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180624040228N3**

Registration date: **2020-04-04, 1399/01/16**

Registration timing: **prospective**

Last update: **2020-04-04, 1399/01/16**

Update count: **0**

##### Registration date

2020-04-04, 1399/01/16

##### Registrant information

##### Name

Fahime Zeinali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 9143

##### Email address

fghzeinaly@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-13, 1399/01/25

##### Expected recruitment end date

2020-07-20, 1399/04/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

An investigation of the topical impact of lemon juice on impulse control of spontaneous nasal bleeding in patients referred to the Emergency Services

**Public title**

Topical impact of lemon juice on impulse control of spontaneous nasal bleeding

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Men and women referred to the emergency department of Shahid Sadoughi and Shahid Rahnemoon Hospitals of Yazd with a diagnosis of spontaneous nasal bleeding The age range of 18-55 years Who wish to participate in the study

**Exclusion criteria:**

Pregnancy Uunderlying liver, kidney and heart disease Hereditary or acquired coagulopathy History of lemon or phenylphrine or lidocaine sensitivity Trauma

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

1.Randomization method: Simple 2.Randomization unit: Personal 3.Randomization device: Random number table .To assign individuals to the intervention and control groups, a random number table will be used.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Cottons containing lemon juice and placebo are similar in shape and appearance, and the bottles of cottons are the same (in terms of color and shape). A and B labels will be fixed on the bottles of Cottons by someone irrelevant to the entire study. participants and researchers will be blinded to the contents in the bottles through out the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

National Committee for Ethics in Biomedical Research

**Street address**

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1234567890

**Approval date**

2019-06-26, 1398/04/05

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1398.100

**Health conditions studied****1****Description of health condition studied**

Spontaneous nasal bleeding

**ICD-10 code**

R04.0

**ICD-10 code description**

Epistaxis

**Primary outcomes****1****Description**

Nasal bleeding

**Timepoint**

5 and 10 minuets and 24 hours after intervention

**Method of measurement**

Physical examination by the physician

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Put cotton containing 2% lidocaine

and lemon juice (5 drops) in the patient's nose

**Category**

Treatment - Drugs

**2****Description**

Control group: Put cotton containing 2% phenylephrine and lidocaine in the patient's nose

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emergency Shahid Rahnemoun Hospital

**Full name of responsible person**

Behzad Zeinaly

**Street address**

Shahid Rahnemoun Hospital, Farokhi street

**City**

Yazd

**Province**

Yazd

**Postal code**

8916886938

**Phone**

+98 35 3626 0001

**Email**

Rahneemounhospital@ssu.ac.ir

**2****Recruitment center****Name of recruitment center**

Emergency Shahid Sadoughi

**Full name of responsible person**

Behzad Zeinaly

**Street address**

Shahid Sadoughi Hospital, Ibn Sina Street, Shahid Ghandi Blvd.

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yazd\_cdc@ssu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Fateme Mojalal

**Street address**

Shahid Sadoughi University of Medical Sciences,  
Shohadaye gomnam Blvd, Alam Sqrt

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Fmodjallal@ssu.ac.ir

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

Yes

**Title of funding source**

Yazd University of Medical Sciences

**Proportion provided by this source**

50

**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**

Yazd University of Medical Sciences

**Full name of responsible person**

Behzad Zeinaly

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Fateme Mojalal

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Behzad Zeinaly

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

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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**

Undecided - It is not yet known if there will be 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