

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effects of phenylephrine spray in patients with nasal fractures closed reduction under general anesthesia

Protocol summary

Summary

Objectives: The purpose of this study is to evaluate the effect of phenylephrine spray is closed reduction of nasal bones fracture in patients referred to the ENT clinic of ValiAsr hospital. Design: The sample size of this study will be 200 people, including 100 cases and 100 cases as control group. The patients will be randomly assigned to each group by using A and B papers by patients. Setting and conduct: Patients will receive pre-anesthesia phenylephrine spray. Blood pressure of all patients before and 5 minutes after the intervention will be measured. Major inclusion and exclusion criteria: All patients with recent nasal bones fractures will be included in the study and patients with septal fractures, open fractures and upper airways infection will be excluded. Intervention: Using phenylephrine spray pre-anesthesia. Main outcome measures (variables): Mean blood pressure before and 5 minutes after the operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030518063N3**

Registration date: **2016-04-01, 1395/01/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-01, 1395/01/13

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research - Birjand University of Medical Sciences

Expected recruitment start date

2016-03-15, 1394/12/25

Expected recruitment end date

2016-05-15, 1395/02/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of phenylephrine spray in patients with nasal fractures closed reduction under general anesthesia

Public title

The effects of phenylephrine spray in patients with nasal fractures closed reduction under general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Recent untreated nasal bones fracture
Exclusion Criteria: Septum fracture; Open fractures; Along with other facial bones broken nose; Conflict or infection of the sinuses; Colds and upper respiratory tract infection

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

دانشگاه علوم پزشکی بیرجند

Secondary trial Id

767

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Birjand University of Medical Sciences

Street address

Moallem Blvd, Birjand, Iran

City

Birjand

Postal code

Approval date

2015-11-11, 1394/08/20

Ethics committee reference number

ir.byms.1394.53

Health conditions studied

1

Description of health condition studied

Nasal Bone Fractures

ICD-10 code

S02.2

ICD-10 code description

Fracture of nasal bones

Primary outcomes

1

Description

Mean Blood Pressure

Timepoint

before intervention - 5 minutes after surgery

Method of measurement

Vital Sign Monitoring

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

case group: treated with phenylephrine spray 30 minutes before undergoing surgery

Category

Treatment - Drugs

2

Description

control group: the patients in this group will not take phenylephrine spray before surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr Hospital

Full name of responsible person

Fahime Gohari

Street address

Moallem Blvd, Birjand, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research - Birjand University of Medical Sciences

Full name of responsible person

Dr. Zarban

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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

Vice-chancellor for research - Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*