

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Sep 2026

Comparative effects of acupuncture and placebo acupuncture in reducing intraoperative bleeding in open rhinoplasty surgery in patients 18 to 45 years, ASA class1 in Vali Asr Operation Room, Imam Khomeini Hospital 1390-91 years, a randomized clinical trial.

Protocol summary

Study aim

The effect of acupuncture in reducing bleeding during open rhinoplasty

Design

patients with ASA class 1 undergoing Open Rhinoplasty Surgery are divided into case and control and placebo groups. each group consists of 44 patients who are selected randomly and double-blinded. In the case group, in addition to controlled hypotension by Remifentanyl and propofol infusion, acupuncture points in the foot area identified by the device are stimulated by the needle. In the control group, patients will only undergo controlled hypotension with remifentanyl, In the placebo group, in addition to controlled hypotension, the points outside the acupuncture canal are stimulated with a needle. Then, parameters such as surgeon satisfaction, the weight of bloody gauze used in the surgical field, intra-suction blood volume and hemoglobin changes before and after surgery in both groups are evaluated

Settings and conduct

Valiasr Hospital

Participants/Inclusion and exclusion criteria

18 to 45-year-old ASA Class I patients scheduled for rhinoplasty surgery

Intervention groups

Each of the three groups includes 44 patients who are randomly selected double-blinded. In the case group, after obtaining patient satisfaction, in addition to controlled hypotension by Remifentanyl and propofol infusion, acupuncture points in the foot area identified by the acuhealth device are stimulated by the needle. In the control group, patients will only undergo controlled hypotension with remifentanyl, In the placebo group, in addition to controlled hypotension, the points outside the acupuncture canal are stimulated with a needle.

Main outcome variables

Reducing intraoperative bleeding

General information

Reason for update

Correction of a possible typographical error in the type of study written retrospective, while RCT is.

Acronym

IRCT registration information

IRCT registration number: **IRCT2013073114238N1**

Registration date: **2013-12-20, 1392/09/29**

Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**

Update count: **1**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

Erfan Sedaghat

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6656 3382

Email address

e-sedaghat@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

2015-02-20, 1393/12/01

Actual recruitment end date

2015-10-23, 1394/08/01

Trial completion date

2015-10-23, 1394/08/01

Scientific title

Comparative effects of acupuncture and placebo acupuncture in reducing intraoperative bleeding in open rhinoplasty surgery in patients 18 to 45 years, ASA class1 in Vali Asr Operation Room, Imam Khomeini Hospital 1390-91 years, a randomized clinical trial.

Public title

Evaluation of the effect of acupuncture in reducing intraoperative bleeding in rhinoplasty.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

candidates for primary open rhinoplasty

Exclusion criteria:

recent treatment with acupuncture, revision surgery, cardiovascular disease (congestive heart failure, coronary artery disease) , cerebrovascular disease, poorly controlled arterial hypertension, history of renal or hepatic insufficiency, history of drug abuse, the presence of a pacemaker, coagulation disorders, neurological disorders, pregnancy patients taking corticosteroid.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **88**

Actual sample size reached: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

computer-generated random number

Blinding (investigator's opinion)

Double blinded

Blinding description

The acupuncture points and needles were covered by drapes in both groups for 30 minutes to make other members of the team blind to the group assignment of patients. Another anesthesiologist, who was blinded to the treatment group allocation, collected the data during the operations.

Placebo

Used

Assignment

Parallel

Other design features

This innovation was first used in the world.

Secondary Ids

empty

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

Tehran University of Medical Science

Street address

Central Department of Tehran university, 6th floor, Ghods avenue, Keshavarz Bolvar

City

Tehran

Province

Tehran

Postal code

149733141

Approval date

2013-11-30, 1392/09/09

Ethics committee reference number

92/130/1954/3

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

intra operative bleeding

ICD-10 code

Z40-Z54

ICD-10 code description

Persons encountering health services for specific procedures and health care

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

intra operative bleeding

Timepoint

Immediately after intervention

Method of measurement

gauze surgical weight with a digital scale and measuring goats milligrams per milliliter of blood volume in the suction and hemoglobin levels before and after surgery and surgeon satisfaction questionnaire

Secondary outcomes

1

Description

reduced mean arterial blood pressure

Timepoint

After intervention and during surgery

Method of measurement

Monitoring the pressure gauge on mmHg

2

Description

Improve richmond criteria in Recovery

Timepoint

after surgery and entering the patient to recovery

Method of measurement

Questionnaire Form

3

Description

improved patient satisfaction who have congestive problems

Timepoint

when the patient leaving recovery

Method of measurement

Questionnaire Form

Intervention groups

1

Description

In all three groups of Method of anesthesia is General Anesthesia and endotracheal intubation .after prepare and Preoxygenation premedication drug Midazolam 0.015 -0.05 mg / kg and opioid (usually Fentanyl (1-2mcg/kg administration and then Intravenous anesthetic Propofol 2 mg / kg and muscle relaxants (Atracurium 0.5-0.6 mg / kg) is administered and intubation with Appropriately sized endotracheal tube is performed.maintenance of anesthesia for all patients, in addition to a percentage of Isoflurane gas inhalation infusion of Ringer ml 1000, induced hypotension with Remifentanyl infusion syringe pump at a dose of 0.5 mcg / kg / min and Propofol 50mcg/kg/min. oxygen and nitrous oxide 50:50 with and Atracurium 10 mg will be given 30 minutes to complete anesthesia. Applied to all patients 1 to 2 mL of 1% lidocaine solution impregnated Adrenaline 1 in 200,000 in the lateral wall nose before surgery by the surgeon will inject.Group I: Patients with induced hypotension to control bleeding only routine infusion (propofol and remifentanyl) are used to them. (Contro group)

Category

Prevention

2

Description

in case group: . For medical treatment Acupuncture in point of LIV-3, SP-1, ST-45, BL-67 with special Disposable Needle Acupuncture CE0197 and FDA certification mark

licensed HUANQIU No. 25 will 510K.011242 numbers. Looking for This points out the PRO900 ACUHEALTH TENS device CE0120 certificate and FDA approval of Australia Will be used.

Category

Prevention

3

Description

Blinding of the surgeon in order to make acupuncture channel points out that By Acuhealth have been identified as areas outside of the channel by the same faculty member with a needle anesthesia Are stimulated.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Operation Room,limam Khomeini Hospital

Full name of responsible person

Dr.Erfan Sedaghat

Street address

3th floor, no 7, Hamsyan Streat, Sadoghi Avenue, north jamalzadeh, tehran, iran

City

Tehran

Province

Tehran

Postal code

149733141

Phone

+98 21 6119 2828

Email

e-sedaghat@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dr.Erfan Sedaghat

Full name of responsible person

Dr.Erfan Sedaghat

Street address

Imam Khomeini Hospital,end of Keshavarz bolvar

City

Tehran

Province

Tehran

Postal code

149733141

Phone

+98 21 6119 2828

Email

e-sedaghat@razi.tums.ac.ir

Grant name

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

Yes

Title of funding source

Dr.Erfan Sedaghat

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

Imam Hospital

Full name of responsible person

Dr.Shahram Samadi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini Hospital,end of Keshavarz bolvar

City

Tehran

Province

Tehran

Postal code

149733141

Phone

+98 21 6658 1576

Fax

Email

shsamadi@yahoo.com

Web page address

City

Tehran

Province

Tehran

Postal code

149733141

Phone

+98 21 6658 1576

Fax

Email

shsamadi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Imam Khomeini Hospital

Full name of responsible person

Dr. Erfan Sedaghat

Position

Resident of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini Hospital, end of Keshavarz Bolvar

City

Tehran

Province

Tehran

Postal code

149733141

Phone

+98 21 6658 1576

Fax

Email

e-sedaghat@razi.tums.ac.ir

Web page address

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam Khomeini Hospital complex

Full name of responsible person

Dr.Shahram Samadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini Hospital, end of Keshavarz Bolvar

Undecided - It is not yet known if there will be a plan to make this available