

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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 Remifentanil 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 remifentanil, 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 Remifentanil 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 remifentanil, 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 Remifentanil 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 remifentanil) 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**

## 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

**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**

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