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 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 Univercity of Medical Science
Street address
Central Department of Tehran univercity, 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/د

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 artrial blood presure
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.maintanance 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,Iimam 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