Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparisonal survey of local infiltration of adrenalized lidocain with adrenaline alone in operative field bleeding in Rhinoplastic surgery

Protocol summary

Summary

In head and neck surgeries, bleeding in surgical field has an important role in decrease of operation time and also it prevents blood transfusion complications. An effective method for decrease blood in surgical field is infiltration of adrenaline. Adrenaline usually diluted with lidocaine, but lidocain has a vasodilator effect. The study compare amount of blood in surgical field between lidocain group and control group (without lidocain). The study is done in patients with ASA class I and II candidate for rhinoplastic surgery; they are divided to two groups (lidocain and control) randomly. In lidocain group adrenaline and 2% lidocain is used and in control group adrenaline and saline. Then the amount of bleeding in surgical field is documented and then compare between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502172946N6**
Registration date: **2015-03-08, 1393/12/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-03-08, 1393/12/17

Registrant information

Name

Mitra Yari

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6310

Email address

myari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparisonal survey of local infiltration of adrenalized lidocain with adrenaline alone in operative field bleeding in Rhinoplastic surgery

Public title

study of effect of lidocain infiltration in surgical field bleeding

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 15-45 years old; ASA class I and II. Exclusion criteria: coagulopathy; heart diseases; hypertension.

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Kermanshah University of Medical Sciences
Street address
No. 2 building of Medical University, Shahid Beheshti boulevard
City
Kermanshah
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
53879

Health conditions studied

1

Description of health condition studied
Amount of bleeding in surgical field
ICD-10 code
Z42.0
ICD-10 code description
Follow-up care involving plastic surgery of head and neck

Primary outcomes

1

Description
The amount of surgical bleeding
Timepoint
Every 10 minute during surgery
Method of measurement
Blood in suction and gauze

Secondary outcomes

1

Description
Surgical field bleeding
Timepoint
Every 10 minute
Method of measurement
Boezaart quality scale of bleeding

Intervention groups

1

Description
In intervention group(lidocain group)adrenaline 1/200000 and 2% lidocain is infiltrated intradermal in surgical field and every 10 minute scale of surgical field bleeding was documented and at the end of operation total amount of bleeding was documented
Category
Prevention

2

Description
In control group adrenaline 1/200000 and saline 0.9% is infiltrated intradermal in surgical field and every 10 minute scale of surgical field bleeding was documented and at the end of operation total amount of bleeding was documented
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Mitra Yari
Street address
Parastar boulevard, Sorkhalijeh
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
No. 2 building of Medical University, Shahid Beheshti boulevard
City
Kermanshah
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Mitra Yari
Position
Associated professor and anesthesiologist
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact

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