Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of hydrogen peroxide and normal saline irrigation on postoperative complications of rhinoplasty in patients undergoing rhinoplasty

Protocol summary

Study aim

comparison of the effects of hydrogen peroxide and normal saline irrigation on postoperative complications of rhinoplasty in patients undergoing rhinoplasty

Design

In this In this study, which is a randomized single-blinded clinical trial, volunteers of rhinoplasty who entered the study with informed written consent were randomly divided into intervention and control groups, and the severity of the complications of both groups at specified intervals after ending of the Surgery is monitored to evaluate the effect of hydrogen peroxide on the prevention of these complications.

Settings and conduct

The present study is a single-blind clinical trial conducted at Arya Hospital of Kermanshah affiliated to Kermanshah University of Medical Sciences. Patients are blind to the type of intervention they will receive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients undergoing rhinoplasty right after the operation. Non inclusion criteria: opioid, drug and alcohol abusers; History of previous or present systemic diseases and continuous use of drugs; daily use of analgesics or using of them 24 hours before the operation; patients who can not cooperate

Intervention groups

Rinoplasty volunteers who enter this study with written consent are randomly divided into normal saline and hydrogen peroxide groups. Immediately after surgery, and before dressing, in the intervention group, the position is washed with 3% hydrogen peroxide and in the control group the position is washed with normal saline.

Main outcome variables

The severity of pain, swelling, edema, ecchymosis, bleeding, inflammation and infection

General information

Reason for update

Modification of some scales and methods that have been done during the study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20140503017537N6**
Registration date: **2019-02-03, 1397/11/14**
Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**
Update count: **1**

Registration date

2019-02-03, 1397/11/14

Registrant information

Name

Hesamedin Nazari

Name of organization / entity

Kermanshah University of Medical Sciences , School of Dentistry

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-05, 1397/12/14

Expected recruitment end date

2019-08-05, 1398/05/14

Actual recruitment start date

2019-03-11, 1397/12/20

Actual recruitment end date
2019-09-11, 1398/06/20
Trial completion date
2019-11-01, 1398/08/10

Scientific title
Comparison of the effects of hydrogen peroxide and normal saline irrigation on postoperative complications of rhinoplasty in patients undergoing rhinoplasty

Public title
The effects of hydrogen peroxide irrigation on postoperative complications of rhinoplasty
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing rhinoplasty right after the operation
Exclusion criteria:
Opioid, drug and alcohol abusers History of previous or present systemic diseases and continuous use of drugs daily use of analgesics or using them 24 hours before the operation Patients who can not cooperate
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **44**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
A random number generation technique will be used in the Excel environment, so that a code is assigned to each patient before starting the study using the random numbers table. Depending on the last digit of the assigned code, the type of treatment being selected. If the last digit of the code is even (0, 2, 4, 6, 8) the patient is placed in the hydrogen peroxide group, and if it is odd, the patient is placed in the control group. By this method, allocation of each patient to the hydrogen peroxide group or normal saline group is accomplished by simple randomization technique
Blinding (investigator's opinion)
Double blinded
Blinding description
A secretary who has no role in the study assigns a code to each patient using the random code table. These codes that identify the patient group are sealed and closed until the completion of the study in an envelope. Therefore, random allocation and allocation concealment is achieved for both the patients as well as the operators, examiners, surgeons and clinicians.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Committee of Ethics in Research - Kermanshah University of Medical Sciences
Street address
Committee of Ethics in Research, Vice chancellor for research and technology, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.
City
Kermanshah
Province
Kermanshah
Postal code
6715847167
Approval date
2018-12-26, 1397/10/05
Ethics committee reference number
IR.KUMS.REC.1397.745

Health conditions studied

1

Description of health condition studied
postoperative complications of rhinoplasty
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
severity of postoperative pain
Timepoint
At intervals 2, 6, 12 to 24 hours after surgery
Method of measurement
using the Visual Analogue Scale(VAS)

2

Description
severity of postoperative swelling
Timepoint
At intervals of 1 week, 2 weeks, 4 weeks and 8 weeks after surgery
Method of measurement
using the Surgeon Periorbital Rating of Edema and

Ecchymosis (SPREE)

3

Description
severity of postoperative edema
Timepoint
On days 1,2,5,7,10 after surgery
Method of measurement
using the Surgeon Periorbital Rating of Edema and Ecchymosis (SPREE)

4

Description
severity of postoperative echymosis
Timepoint
On days 1,2,5,7,10 after surgery
Method of measurement
using the Surgeon Periorbital Rating of Edema and Ecchymosis (SPREE)

5

Description
amount of postoperative bleeding
Timepoint
On the first day after surgery
Method of measurement
Counting the number of dressing needed

6

Description
severity of postoperative inflammation
Timepoint
During the first week after surgery
Method of measurement
using the +-

7

Description
severity of postoperative infection
Timepoint
During the first week after surgery
Method of measurement
using the +-

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After the operation has finished, before dressing the wound , the surgical field is washed with hydrogen peroxide (3%) (which is made immediately before the process and kept in good condition away from light).
Category
Treatment - Drugs

2

Description
Control group: After the operation has finished, before dressing the wound , the surgical field is washed with normal saline.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arya Hospital of Kermanshah
Full name of responsible person
Hessamedin Nazari
Street address
Bahar Ave, Kermanshah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Vice chancellor for research and technology, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.
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Email
fnajafi@kums.ac.ir
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
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
Kermanshah University of Medical Sciences

Full name of responsible person
Hesamedin Nazari

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There are no further information available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available