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 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
Rhinoplasty 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

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.

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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

Description of health condition studied
postoperative complications of rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

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)

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
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 ecchymosis

**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**
Arya Hospital of Kermanshah

**Full name of responsible person**
Hessamedin Nazari

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Bahar Ave, Kermanshah

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**Province**
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Sponsors / Funding sources

1

**Sponsor**
Kermanshah University of Medical Sciences

**Full name of responsible person**
Farid Najafi

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Vice chancellor for research and technology, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

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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
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Position
Assistant professor
Latest degree
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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

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Person responsible for updating data
Contact
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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
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No - There is not a plan to make this available