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

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)

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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Kermanshah
Province
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Postal code
6713954658
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http://aryahospitalksh.com

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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Postal code
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Phone
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Email
fnajafi@kums.ac.ir
Grant name

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).
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

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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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