Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the skin effects of pretreatment preparation with chlorhexidine solution and povidone-iodine before rhinoplasty: a randomized clinical trial

Protocol summary

Study aim
Comparison of the skin effects of pretreatment preparation with chlorhexidine solution and povidone-iodine before rhinoplasty

Design
Clinical trial,two interventional group, blinded patients and the assesor, randomization, allocation proportion 1:1 on 42 patients. randomization is doing with exel soft ware RANDBETWEEN.

Settings and conduct
Patients are in two groups includig chlorhexine and povidone-iodine, and prepping 21persons with chlorhexidine and 21 persons with povidone-iodine before surgery. open rhinoplasty surgery is doing by one surgeon in noor surgical clinic. blinding is in two level: patients and the assesor.

Participants/Inclusion and exclusion criteria
Patients who are candidates for rhinoplasty surgery

Intervention groups
First intervention group: prepping the patient's face with chlorhexidine before surgery second intervention group: prepping the patient's face with povidone-iodine before surgery

Main outcome variables
Erythema; Itching

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211121053135N1**
Registration date: **2022-02-06, 1400/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-06, 1400/11/17**
Update count: **0**

Registration date
2022-02-06, 1400/11/17

Registrant information

Name
Hooshyar Abbasi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3729 2254

Email address
hoshyar7ab@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the skin effects of pretreatment preparation with chlorhexidine solution and povidone-iodine before rhinoplasty: a randomized clinical trial

Public title
Comparison of the skin effects of pretreatment preparation with chlorhexidine solution and povidone-iodine before rhinoplasty: a randomized clinical trial

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:

ASA I or II health status. The patient is ready to take part in the study and sign the testimonial.

Exclusion criteria:

History of underlying diseases affecting the wound healing process like systemic diseases(diabetes, high blood pressure, gastrointestinal system diseases, kidney disorders, heart and lung diseases) Current consumption of drugs, alcohol, opiums (consumption of any of these substances during the last month) Pregnant women Any allergies or Hypersensitivities to the drugs used in this study

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers are generated using Excel software by a statistician to do this. Four-digit codes are generated. A four digit code is allocated to each patient and the last digit on the right indicates the patient group. if the number obtained is odd(1,3,5,7,9), the patient is in the chlorhexidine group and if the number is even(0,2,4,6,8), the patient is in the povidone-iodine group Each of the generated codes is kept separately inside the envelope and the receptionist gives one of these envelopes to the patient before entering the operating room. Accordingly, the next patient code is not predictable. Based on the patient's code, the physician determines which treatments to implement, Only the physician who implements the intervention knows the code allocated to the patient, which after evaluating the outcome, based on thepatient's name, the information collected will be related to the assigned codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding is performed in 2 levels including the patient and outcome assessor . As the irrigation with chlorhexidine and povidone-iodine is done while anesthesia , the patient is uninformed about the kind of intervention. Also the outcome assessor who is the dermatologist is uninformed about the kind of patients intervention. Therefore in this study both the patient and the outcome assessor are uninformed about the kind of patient intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Science

Street address

Mohamadi Ave., Amirkabir Blvd., Kermanshah Town

City

Kermanshah

Province

Kermanshah

Postal code

6714738178

Approval date

2022-01-29, 1400/11/09

Ethics committee reference number

IR.KUMS.REC.1400.754

Health conditions studied

1

Description of health condition studied

Urticaria

ICD-10 code

L50

ICD-10 code description

Urticaria

2

Description of health condition studied

Erythema

ICD-10 code

B08.3

ICD-10 code description

Erythema infectiosum [fifth disease]

3

Description of health condition studied

Acne

ICD-10 code

L70

ICD-10 code description

Acne

4

Description of health condition studied

Macula

ICD-10 code

ICD-10 code description

Macula

5

Description of health condition studied
Papula
ICD-10 code
ICD-10 code description
Papula

6

Description of health condition studied
Plaque
ICD-10 code
ICD-10 code description
Plaque

7

Description of health condition studied
Seborrheic dermatitis
ICD-10 code
L21
ICD-10 code description
Seborrheic dermatitis

8

Description of health condition studied
Perioral dermatitis
ICD-10 code
L71.0
ICD-10 code description
Perioral dermatitis

9

Description of health condition studied
Allergic contact dermatitis
ICD-10 code
L23
ICD-10 code description
Allergic contact dermatitis

10

Description of health condition studied
Itching
ICD-10 code
ICD-10 code description
Itching

11

Description of health condition studied
Burning
ICD-10 code
ICD-10 code description
Burning

12

Description of health condition studied
Scabbing
ICD-10 code
ICD-10 code description
Scabbing

Primary outcomes

1

Description
Initial outcome will be contain of erythema
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
Erythema will be studied on the basis of dermatologist opinion in this way: without, light, moderate and severe erythema.

2

Description
Initial outcome will be contain of itching
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
Itching will be studied on the basis of ten parts scale Visual Analogue Scale with asking from patient

Secondary outcomes

1

Description
Secondary outcome is containing of burning
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
Burning will be studied on the basis of ten parts scale Visual Analogue Scale with asking from patient

2

Description
Secondary outcome is containing of acne
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
They will be studied on the basis of dermatologist opinion in 4 group: without, slight, moderate and severe events.

3

Description
Secondary outcome is containing of urticaria
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
They will be studied on the basis of dermatologist

opinion in 4 group: without, slight, moderate and severe events.

4

Description
Secondary outcome is containing of macula
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
They will be studied on the basis of dermatologist opinion in 4 group: without, slight, moderate and severe events.

5

Description
Secondary outcome is containing of papula
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
They will be studied on the basis of dermatologist opinion in 4 group: without, slight, moderate and severe events.

6

Description
Secondary outcome is containing of allergic contact dermatitis
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
They will be studied on the basis of dermatologist opinion in 4 group: without, slight, moderate and severe events.

7

Description
Secondary outcome is containing of perioral dermatitis
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
They will be studied on the basis of dermatologist opinion in 4 group: without, slight, moderate and severe events.

8

Description
Secondary outcome is containing of seborrheic dermatitis
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
They will be studied on the basis of dermatologist opinion in 4 group: without, slight, moderate and severe events.

9

Description
Secondary outcome is containing of plaque
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
They will be studied on the basis of dermatologist opinion in 4 group: without, slight, moderate and severe events.

10

Description
Secondary outcome is containing of scabbing
Timepoint
Patients will be studied about skin effects 3 days later, one week later and one month later after surgery.
Method of measurement
They will be studied on the basis of dermatologist opinion in 4 group: without, slight, moderate and severe events.

Intervention groups

1

Description
Intervention group (first): in chlorhexidine group, face prepping before surgery is done by 2% chlorhexidine.one surgeon operate them with open method and with midazolam induction, narcotic(fentanyl), atracurium(laxative) and propofol on the basis of person's per kilogram, and the surgery duration is about 1/5 hour and after that all the patients have tampon for 3 days, in addition to they have splint and mesh for one week on their nose.
Category
Prevention

2

Description
Intervention group(second): in povidone-iodine group, face prepping before surgery is done by 10% povidone-iodine. one surgeon operate them with open method and with midazolam induction, narcotic(fentanyl), atracurium(laxative) and propofol on the basis of person's per kilogram, and the surgery duration is about 1/5 hour and after that all the patients have tampon for 3 days, in addition to they have splint and mesh for one week on their nose.
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Noor Specialized Surgical Center

Full name of responsible person
Dr Shahram Abbasabadi

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Azadi Sq, Modares Ave, Kermanshah Town

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http://www.noortebclinic.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Zohreh Rahimi

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school of dentistry,Shariati Ave

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http://dentistry-school.kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Kermanshah University of Medical Science

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
Hoshyar Abbasi

Position
Associated professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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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