

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 assessor, randomization, allocation proportion 1:1 on 42 patients. randomization is doing with excel software RANDBETWEEN.

Settings and conduct

Patients are in two groups including chlorhexidine and povidone-iodine, and prepping 21 persons 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 assessor.

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)

Phone

+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, opioms (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 the patient'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

Street address

Azadi Sq, Modares Ave, Kermanshah Town

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Email

saba.ahmadi.den@gmail.com

Web page address

<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

Street address

school of dentistry, Shariati Ave

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saba.ahmadi.den@gmail.com

Web page address

<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

Contact

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Kermanshah University of Medical Sciences

Full name of responsible person

Hoshyar Abbasi

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Specialist

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Person responsible for updating data

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Full name of responsible person

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Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

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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