

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Head position on swelling and ecchymosis after Rhinoplasty operation on patient who visited surgery clinics

Protocol summary

Study aim

Determining the effect of head position on ecchymosis and swelling after rhinoplasty

Design

clinical trial ,with control and intervention groups ,single blinded , Balanced Block Randomization

Settings and conduct

Facial plastic surgery clinic in patients undergoing rhinoplasty; in the intervention group,the position of the head was kept 40 to 60 degrees higher after surgery, and then both groups will be followed up for one week.

Participants/Inclusion and exclusion criteria

inclusion criteria: Rhinoplasty candidates
exclusion criteria: underlying disease, cardiopulmonary disease, taking drugs ASA and OCP

Intervention groups

In intervention group will performed head position; in the form of head elevation 40-60 degrees.(on the second day after rhinoplasty until the seventh day) control groups: no intervention

Main outcome variables

ecchymosis ; swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201005048938N1**

Registration date: **2020-10-30, 1399/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-30, 1399/08/09**

Update count: **0**

Registration date

2020-10-30, 1399/08/09

Registrant information

Name

ناصری Halime

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3764 4622

Email address

ftm.naseri@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-15, 1399/07/24

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Head position on swelling and ecchymosis after Rhinoplasty operation on patient who visited surgery clinics

Public title

The effect of Head position on swelling and ecchymosis after Rhinoplasty operation

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

having conscious satisfaction with the objectives of the research lack of underlying disease including coagulation disorder and cardiopulmonary disease dont take contraceptive agent and aspirin before surgery

Exclusion criteria:

Cardiopulmonary disease Coagulopathy disease Using
contraceptive agent and ASA before Rhinoplasty

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
balanced Block Randomization with 10 balanced block. patients randomly will be allocated into 2 groups that each group will include 60 people. we included 120 patients (who 60 of them recipient intervention (head elevation) and 60 each other have not intervention); there will be 5 cards in each group; So in each groups ,10 patients are assigned as midwives.

Blinding (investigator's opinion)
Single blinded

Blinding description
In order to eliminate the bias caused by the knowledge of the researcher and clinical evaluator and data analyzer and its possible effect on the research result, this study performed single blind; And the data evaluator and the person analyzing data do not know that patients are constantly in intervention or control groups.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zahedan University of Medical Science

Street address
dr Hesabi Blvd, university of Zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816746557

Approval date

2020-07-25, 1399/05/04

Ethics committee reference number
IR.ZAUMS.REC.1399.157

Health conditions studied

1

Description of health condition studied
edem and ecchymosis after rhinoplasty

ICD-10 code
Z41

ICD-10 code description
Encounter for procedures for purposes other than remedying health state

Primary outcomes

1

Description
edem

Timepoint
evaluating of periorbital edema in 2th day after intervention in 3,5,7

Method of measurement
standard four-point scoring tool

2

Description
Ecchymosis

Timepoint
evaluation of periorbital ecchymosis in 2th day after intervention in 3,5,7

Method of measurement
standard four-point scoring tool

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: head elevation after rhinoplasty of 40 to 60 degrees , which will be recommended to patients by a cosmetic surgeon. Keeping the head high is one of the most common post-rhinoplasty care that is given to patients by cosmetic surgeons. Decreased blood flow and reduce inflammation that decrease edema and ecchymosis . This procedure will be performed for a week in patients whose head position is 40-60 degrees when holding the head while lying down and sleeping.

Category
Treatment - Other

2

Description

Control group: have not intervention
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa and Noor surgery clinics in zahedan

Full name of responsible person

Dr Mohammad Zare

Street address

Shafa surgery clinic ,Khayam aven,Zahedan

City

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Province

Sistan-va-Balouchestan

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9817643429

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+98 54 3342 7999

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shafaclinic@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr.NoorMohammad Bakhshani

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Zahedan University of Medical Sceince

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Province

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admin&finance@zaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Halime Naseri

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Halime Naseri

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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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