

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of oral administration of Clonidine on pain control in patients after Rinoplasty

Protocol summary

Study aim

The purpose of this study was to investigate the effect of oral administration of clonidine on pain control in patients undergoing Rinoplasty

Design

This randomized double blind clinical trial with parallel groups will be conducted among 40 patients. The study phase is 2-3. Using random numbers table participants will be divided into two equal groups: A (intervention group) and B (control group). In group A, the patients will receive clonidine and group B, will take the placebo.

Settings and conduct

This study will be done at the maxillofacial surgery department of imam khomeini hospital. The number of Participants will be 40 people. The patients and researcher don't know who is in what group. Pills will be provided in the same packs by the drug center. To the intervention and the control groups, clonidine and placebo will be given respectively. The mount of pain will be evaluated by VAS scale, blood pressure in 24 hours and ecchymosis amount in first third and seventh days and number of analgesic pill and analgesia time interval will be recorded

Participants/Inclusion and exclusion criteria

inclusion criteria: rhinoplasty candidate, age above 20 year and people without systemic disease. exclusion criteria: allergy to clonidine, liver, kidney and heart disease and high blood pressure

Intervention groups

"Intervention group": The volunteers in this group will be given the clonidine pill. "Control group": They will receive the Placebo. (The placebo contains starch). The participants in both groups must eat pill 60-90 minutes before operation

Main outcome variables

pain, blood pressure, ecchymosis amount in every anatomic area, analgesic pills number, analgesia time interval

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180601039936N1**

Registration date: **2019-08-03, 1398/05/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-03, 1398/05/12**

Update count: **0**

Registration date

2019-08-03, 1398/05/12

Registrant information

Name

Marziye Ghanemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3337 4778

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marzie.ghanemi.19@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-11, 1398/04/20

Expected recruitment end date

2019-08-11, 1398/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral administration of Clonidine on pain control in patients after Rhinoplasty

Public title

effect of clonidine in rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

rhinoplasty candidate people without systemic disease
people with twenty aged and above people without
systemic disease

Exclusion criteria:

Age

From **20 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study the randomization will be done using random numbers table. After consultation with the statistics specialist even numbers will be considered for the intervention group and odd numbers for control group. The researcher stays on one of the numbers then the right direction which predefined to move and the numbers will be registered.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and researcher will not be aware of the type of treatment. The first clonidine and placebo pill that contain starch (same to clonidine in shape and color) will be bought from drug store. Then the nurse will place the clonidine and pantoprazole in the same pack. Only the nurse will be aware of the type of content inside packs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Ahvaz Jundi Shapur University Of
Medical Sciences

Street address

Jundi Shapur University Of Medical Sciences, Golestan
Street

City

Ahvaz

Province

Khouzestan

Postal code

6135715775

Approval date

2018-07-14, 1397/04/23

Ethics committee reference number

IR.AJUMS.REC.1397.316

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

pain

Timepoint

first 24 hours

Method of measurement

The pain status of patients is measured using the Visual Analog Scale (VAS), and patients are asked to specify a range of 0 to 10 for their pain levels

2

Description

blood pressure

Timepoint

in first 24 hours

Method of measurement

blood pressure recorded in intervals

3

Description

ecchymosis amount

Timepoint

ecchymosis was recorded in first third and seventh day after operation

Method of measurement

ecchymosis in every anatomical area has one point and grading was from zero to thirteen

4

Description

analgesic amount request

Timepoint

in first 24 hours

Method of measurement

analgesic request from patients that was paracetamol (acetaminophen) was recorded

5

Description

analgesic time

Timepoint

in first 24 hours

Method of measurement

analgesic period that equal to no analgesic request was recorded

Secondary outcomes

1

Description

Ecchymosis amount

Timepoint

Ecchymosis was recorded in first third and seventh day after operation

Method of measurement

Ecchymosis in every anatomical area has one point and grading was from zero to thirteen

Intervention groups

1

Description

Intervention group: they must use the 0.2 mg clonidine pill 60-90 minutes before operation

Category

Treatment - Drugs

2

Description

Control group: they must use the placebo pill 60-90 minutes before operation

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Khomeini Hospital Of Ahvaz

Full name of responsible person

Dr Saeed Shirafkan

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Imam Khomeini Hospital, 24 Meter Street

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohammad Mousavi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Saeed Shirafkan

Position

Asistant Professor Of Oral And Maxillofatioal Surgery

Latest degree

Specialist

Other areas of specialty/work

Medical Education

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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

no more information

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