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 emount 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 anathomic 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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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 Rinoplasty

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 contatin startch (same to clonidine in shape and color) will be buyed 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
Street address
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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Jundi Shapur University Of Medical Sciences, Golestan street
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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