

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Oral Melatonin, Vitamin C and Clonidine on the Hemodynamic Response to Endotracheal Intubation, Anesthetic Requirements and Pain after Septorhinoplasty

Protocol summary

Study aim

Comparison of the effect of melatonin, vitamin C and oral clonidine on hemodynamic response

Design

A double-blind, randomized, phase 0 clinical trial study on 120 patients, randomization using a computer-generated random number table.

Settings and conduct

The current study is a randomized study conducted in the general operating room of Imam Khomeini Teaching Hospital in Ahvaz, the research community in this study includes patients who are candidates for septorhinoplasty surgery, general anesthesia and endotracheal intubation, the patients are randomly assigned to three groups of melatonin (group M), vitamin C (group C) and clonidine (group Cl) will be divided and allocation concealment will be done using sealed opaque envelopes.

Participants/Inclusion and exclusion criteria

Age group 18-40 years old, physical condition I-II of the American Society of Anesthesiology, candidate for general anesthesia and endotracheal intubation, physical condition III or above of the American Society of Anesthesiology, mental illness, alcohol abuse, physical problem (heart, liver, kidney, allergic)

Intervention groups

One day before surgery, all patients will undergo a detailed evaluation of preoperative anesthesia and will be kept fasting for eight hours according to the ASA standard protocol. Each group of patients will receive two tablets 120 minutes before induction of anesthesia. All patients 1 They will receive milligrams of midazolam as a pre-medication. The pain level of all patients will be recorded based on a 10-point VAS scale.

Main outcome variables

Monitoring changes in hemodynamic response to laryngoscopy and endotracheal intubation after receiving

oral melatonin, vitamin C, and clonidine, the amount of need for anesthetic drugs, the amount of pain in patients after septorhinoplasty in PACU based on a 10-point VAS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050463N2**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

Registration date

2023-06-26, 1402/04/05

Registrant information

Name

Noushin Sarvi Sarmeidani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3390 6395

Email address

sarvi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

2023-08-23, 1402/06/01
Actual recruitment end date
 2023-08-23, 1402/06/01
Trial completion date
 2023-11-22, 1402/09/01

Scientific title
 Comparison of the Effect of Oral Melatonin, Vitamin C and Clonidine on the Hemodynamic Response to Endotracheal Intubation, Anesthetic Requirements and Pain after Septorhinoplasty

Public title
 Comparison of the effects of melatonin, vitamin C and oral clonidine on the patient's hemodynamic response during anesthesia and afterwards to pain in septorhinoplasty surgery.

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 The age group is 18-40 years Physical status I-II American Society of Anesthesiology Candidate for general anesthesia and endotracheal intubationCommunity Verified icon
Exclusion criteria:
 Physical status III and above American Society of Anesthesiology History of cognitive and mental disorders (dementia, severe depression)Community Verified icon Patients who take anti-anxiety, sedative, anti-psychotic or anti-epileptic drugs. History of circadian rhythm disorders such as chronic fatigue syndrome and sleepiness History of chronic pain syndromes Body mass index more than 30 kg/m² History of difficult airway (Cormack Lehan grade [1] 2 or higher) or more than one intubation attemptCommunity Verified icon History of obstructive sleep apnea and severe asthmaCommunity Verified icon History of drug or alcohol abuse History of congestive heart failure, heart block or bradycardia History of liver or kidney failure History of allergic reaction to studied drugsCommunity Verified icon Patients who have difficulty communicating.Community Verified icon If the patient moves during laryngoscopy or intubation.Community Verified icon

Age
 From **18 years** old to **40 years** old

Gender
 Both

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: **120**
 Actual sample size reached: **120**

Randomization (investigator's opinion)
 Randomized

Randomization description
 . Using a table of random numbers generated by the computer, eligible patients will be randomly divided into three groups: melatonin (M group), vitamin C (C group) and clonidine (Cl group) and allocation concealment

using envelopes. sealed matte will be done. Both the patient and the researcher will be unaware of the type of drug. The patients in the melatonin group received two tablets (3 mg each), the patients in the vitamin C group received two tablets (1 g each), and the patients in the clonidine group also received two tablets (0.1 mg each) 120 minutes before induction of anesthesia. will do The study drugs in all three groups will be the same in terms of size and color and will be given to the patient by the nursing staff in the ward.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Ahwaz Jundishapur University of Medical Sciences

City

ahvaz

Province

Khouzestan

Postal code

6143975617

Approval date

2023-05-13, 1402/02/23

Ethics committee reference number

IR.AJUMS.REC.1402.091

Health conditions studied

1

Description of health condition studied

Determining the effect of oral melatonin, vitamin C and clonidine on the hemodynamic response to laryngoscopy and endotracheal intubation, the need for anesthetics and pain after septorhinoplasty.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determining the effect of melatonin, vitamin C and oral

clonidine on hemodynamic response

Timepoint
Continuously at baseline (T0), 120 minutes after study drug administration, upon entering the operating room (T1), after induction of anesthesia (T2), just before laryngoscopy and endotracheal intubation (T3), after Intubation at intervals of 1 minute (T4), 3 minutes (T5), 5 minutes (T6), 10 minutes (T7) and 15 minutes (T8)

Method of measurement
Operating room monitoring device

Secondary outcomes

1

Description
Reducing the use of anesthetics and postoperative painCommunity Verified icon

Timepoint
During and after the operation

Method of measurement
VAS

Intervention groups

1

Description
Intervention group:

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
General operating room of Imam Khomeini Teaching Hospital, Ahvaz

Full name of responsible person
ali khalafi

Street address
Ahvaz Jundishapur University

City
ahvaz

Province
Khouzestan

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6143975617

Phone
+98 61 3390 6395

Email
nooshinsarvi9192@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person
Ali Biranvand

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Grant name

Grant code / Reference number

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

Title of funding source
Research committee of Ahvaz Jundishapur 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
Noushin Sarvi Sarmeidani

Position
faculty (master's degree)

Latest degree
Master

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Noushin Sarvi Sarmeidani

Position

science Committee

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

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Latest degree

Master

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