Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Preemtive effect of intra venus Diphenhydramin injection before induction of anesthesiaon on attenuating airway and cardiovasculare reflexes during extubation of the endotracheal tube in Orthognathic Surgery.

Protocol summary

Study aim
Evaluation effects of IV Diphenhydramine injection before induction of anesthesia on attenuating airway and cardiovasculare reflexes during extubation of the endotracheal tube in Orthognathic Surgery.

Design
Clinical trial with control group, parallel groups, double-blind, randomized, phase 2 on 70 patients.The software rand function was used to randomize.

Settings and conduct
Patients who are candidates for orthognathic surgery in the operating room with the Computer Generated Table technique are divided into two groups: Diphenhydramine (D) and Placebo (P).Before induction of anesthesia Diphenhydramine 0.6 mg / kg (maximum 50 mg) diluted in 5cc syringe (1cc = 10mg) is injected intravenously (IV) and in the placebo group, the same volume of 5 cc normal saline is injected.Anesthesia is the same in both groups Before incision , all patients receive 0.1 mg / kg morphine sulfate slowly intravenously within two minutes. The degree of sedation based on the Ramsy sedation scale, hemodynamic changes and the incidence of coughing during extubation, severity of pain based on (vissule analoge scale) and the incidence of nausea and vomiting . The need for analgesia in recovery and 24 hours after surgery is also assessed and recorded. Paracetamol is used for postoperative analgesia.

Participants/Inclusion and exclusion criteria
inclusion criteria:1-Age,18-70 years old.2-Elective orthognathic surgery. Exclusion criteria:1-Drug Addiction 2. History of Heart, Kidney and Liver failure, Prostate hyperplasia and Glaucoma .3- History of use of anti-nausea and vomiting drugs

Intervention groups
Intervention group: they take Diphenhydramine IVbefore induction to reduce hemodynamic changes ,agitation during extubation and postoperative pain. Control group: takes normal saline

Main outcome variables
Degree of sedation, severity of pain, cough, nausea and vomiting, hemodynamic changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130304012695N3**
Registration date: **2020-06-01, 1399/03/12**
Registration timing: **retrospective**

Last update: **2020-06-01, 1399/03/12**
Update count: **0**

Registration date
2020-06-01, 1399/03/12

Registrant information

Name
mohammadreza khajavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6312 1220

Email address
khajavim@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-06, 1398/04/15

Expected recruitment end date
2020-02-19, 1398/11/30
Actual recruitment start date
2019-07-11, 1398/04/20
Actual recruitment end date
2020-02-19, 1398/11/30
Trial completion date
2020-02-20, 1398/12/01

Scientific title
Preemtive effect of intra venus Diphenhydramin injection before induction of anesthesiaon on attenuating airway and cardiovasculare reflexes during extubation of the endotracheal tube in Orthognathic Surgery.

Public title
Preemtive effect of intra venus Diphenhydramin injection before induction of anesthesiaon on attenuating airway and cardiovasculare reflexes during extubation of the endotracheal tube in Orthognathic Surgery.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients who are candidates for elective orthognathic surgery
Exclusion criteria:
Drug addiction cardiac ischemia renal and hepatic dysfunction history of large prostate history of postoperative vomiting glaucoma
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **72**
Actual sample size reached: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize patients with inclusion criteria Block balanced randomization is used.Before studying, one of the person who is not a member of the research team performs the randomization process by using Random generator software, forms four blocks for the intervention and control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The person who makes the medicine add a code to every single medicine . The person who injects the drug does not know the code. The patient is not aware of the type of injectable medication. The researcher is not aware of the type of drug during the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Sina Hospital, Imam Khomeini st.
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2019-07-06, 1398/04/15
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.287

Health conditions studied

1

Description of health condition studied
Pain after maxillofacial surgery
ICD-10 code
S02.8
ICD-10 code description
Fractures of other specified skull and facial bones

2

Description of health condition studied
Pain and agitation after maxillofacial surgery
ICD-10 code
K07.5
ICD-10 code description
Dentofacial functional abnormalities

Primary outcomes

1

Description
severity of postoperative pain
Timepoint
During extubation and 5, 15, 30 and 60 minutes after surgery
Method of measurement
Visual Analogue Scale

2

Description
severity of postoperative agitation
Timepoint
During extubation and 5, 15, 30 and 60 minutes after surgery
Method of measurement
Ramsy sedation Scale

Secondary outcomes

1

Description
Hemodynamic changes
Timepoint
During extubation and 5, 15, 30 and 60 minutes after surgery
Method of measurement
blood pressure and Heart Rate

Intervention groups

1

Description
Intervention group: 50 mg of diphenhydramine is injected intravenously before anesthesia and the degree of agitation, pain,coughing and hemodynamic changes during extubation, and the severity of pain in the recovery, nausea and vomiting and the amount of analgesic are evaluated during 24 hours after surgery.
Category
Prevention

2

Description
Control group: They do not receive medication
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Mohammad Reza Khajavi
Street address
Sina Hospital Imam khomeini st
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8550
Email
khajavim@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
Keshavarz Blvd., corner of Quds St., Central Organization of Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Khajavi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Sina Hospital Imam Khomeini st
City
Tehran
Province

Tehran

Postal code
1136746911

Phone
+98 21 6312 1220

Email
khajavim@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Reza Khajavi

Position
Professor

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+98 21 6312 8550

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khajavim@tums.ac.ir

Person responsible for updating data

Contact

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Tehran University of Medical Sciences

Full name of responsible person
Mohammad Reza Khajavi

Position
Professo

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khajavim@tums.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is 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

Title and more details about the data/document
Undecided - It is not yet known if there will be a plan to make this available

When the data will become available and for how long
Undecided - It is not yet known if there will be a plan to make this available

To whom data/document is available
It is not yet known if there will be a plan to make this available

Under which criteria data/document could be used
It is not yet known if there will be a plan to make this available

From where data/document is obtainable
It is not yet known if there will be a plan to make this available

What processes are involved for a request to access data/document
It is not yet known if there will be a plan to make this available

Comments