Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Apotel and Magnesium Sulfate analgesics on pain and Pethidine dose after Maxillofacial surgery.

Protocol summary

Study aim
Comparing the effect of Apotel and Magnesium Sulfate on pain and Pethidine consumption in patients with Maxillofacial surgery.

Design
Phase 2-3 double-blind randomized prospective clinical trial with using Randomize on 60 patients.

Settings and conduct
It will be examined in Bu Ali Hospital in 1400. Researchers and patients are considered blind. One hour before the end of surgery in group A, Apotel is infused within 20 minutes. In group B, 50 kg / mg of magnesium sulfate is infused. Before discharge from the recovery, you will be asked about the pain and its severity based on Visual Analogue Scale (VAS), and in the relevant section, you will be asked every 4 hours for the next 12 hours. It is prescribed at a dose of 30 mg. The total dose of Pethidine is recorded postoperatively, and individuals who received Pethidine at any time during the 12-hour study were excluded from comparing the pain between the two study groups and will be compared separately.

Participants/Inclusion and exclusion criteria
Admission: Absence of severe drug sensitivities; Men and Women 45-18 years; ASA class I and II anesthesia; Informed to study; Candidates for Maxillofacial surgery; Reoperatio or Emergency or Multiple Trauma Not dependent on drugs; Alcohol or Psychedelics. Absence: Serious cardiac arrhythmia and severe arrhythmia; Chronic treatment with Corticosteroids or Calcium channel blockers or NSAIDs; Severe Liver and Kidney diseases, severe anemia.

Intervention groups
Apotel injection to evaluate its analgesic effect on patients with maxillofacial surgery. Injection of Magnesium Sulfate to evaluate its analgesic effect on patients with maxillofacial surgery.

Main outcome variables
Postoperative pain after injection of Apotel and Magnesium Sulfate after surgery, Dosage of pethidine after injection of opotel and magnesium sulfate after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201113049375N1**
Registration date: **2021-09-10, 1400/06/19**
Registration timing: **prospective**

Last update: **2021-09-10, 1400/06/19**
Update count: **0**

Registration date
2021-09-10, 1400/06/19

Registrant information

Name
Mahdi Khalili

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2268 6549

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-03-18, 1400/12/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Apotel and Magnesium Sulfate analgesics on pain and Pethidine dose after Maxillofacial surgery.

Public title
The effect of injectable Acetaminophen and Magnesium Sulfate on pain after Maxillofacial surgery.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Men and Women 45 - 18 years American Society of Anesthesiologists (ASA) Class I and II anesthesia Patients have informed consent to study Candidate for Maxillofacial surgery No Maxillofacial reoperation or Emergency or Multiple trauma
Exclusion criteria:
Having any severe drug allergies . . . . . Be addicted to drugs, alcohol and psychedelics Severe liver and kidney disease or severe anemia Serious heart rhythm disorder and severe arrhythmia Chronic treatment with corticosteroids or calcium channel blockers or NSAIDs

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
A prospective, randomized, double-blind, single type and individual clinical trial using sealed envelopes. The total number of drugs (30 Apoteles and 30 Magnesium Sulfate) is sealed in white bags and then randomly placed from 1 to 60 pieces. We do not know what medicine is in which package. Numbers 1 to 60 are written on the cards. The patient selects the card. The anesthesiologist reads the number on the card and select the envelope which has the number on the card, opens the envelope during the surgery and is informed of the type of medicine, writes the number on the patient's form, and writes the code and type of medicine in the patient's file. The file is archived in the surgery department so that the researcher enters the type of medicine at the end of the sampling by referring to the file. In this way, we will have two groups of 30 people that were randomly divided.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs are sealed in coded envelopes and delivered to the anesthesiologist. In any surgery, the anesthesiologist and surgeon are aware of the type of medication. The anesthesiologist records the code in the patient file. Blinding patients is in such a way that explanations about the study are given and consent is given, but they are unaware of the type of prescription drug. The clinical caregiver and researcher is a person who is unaware of the type of prescription drug (is blind). While caring for the patient, the nurse and resident are unaware of the type of drug (blind). Only the drug code is mentioned in the form. Finally, the researcher enters the patient's file, based on the drug code, enters the type of drug in each patient's form.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the School of Dentistry - Tehran Islamic Azad University of Medical Sciences.
Street address
No. 2/1، Yaghoot Building, Yaghoot Alley, Hosseini Alley, Saba Blvd، Andarzgoo St، Tehran ..
City
Tehran
Province
Tehran
Postal code
1933865311

Approval date
2019-04-21, 1398/02/01

Ethics committee reference number
IR.IAU.DENTAL.REC.1398.005

Health conditions studied

1

Description of health condition studied
Post surgical pain control in Maxillofacial surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain rate in Apotel group

Timepoint
Measurement of pain after injection of Apotel in patients with Maxillofacial surgery in recovery, 4, 8 and 12 hours after recovery.
Method of measurement
Visual Analogue Scale questionnaire.

2

Description
Pain rate in Magnesium Sulfate group
Timepoint
Measurement of pain after injection of Magnesium Sulfate in patients with Maxillofacial surgery in recovery, 4, 8 and 12 hours after recovery
Method of measurement
Visual Analogue Scale questionnaire.

3

Description
Need for use of opioid in the Apotel group
Timepoint
Measurement of the need for opioid use after Apotel injection in patients with Maxillofacial surgery in recovery, 4, 8 and 12 hours after recovery
Method of measurement
Depending on the patient's needs for 30 mg of Pethidine at a time

4

Description
Need for use of opioids in the group of Magnesium Sulfate
Timepoint
Measurement of the need for opioid use after magnesium sulfate injection in patients with Maxillofacial surgery in recovery, 4, 8 and 12 hours after recovery
Method of measurement
Depending on the patient's needs for 30 mg of Pethidine at a time

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients receiving Apotel one gram, Acetaminophen 50 ml, Alborz daroo, One gram is injected to the patient one hour before the end of surgery.
Category
Treatment - Drugs

2

Description
Intervention group 2: Magnesium sulfate 50 mg / kg, Shahid Ghazi Tabriz, 50 mg / kg is injected to the patient one hour before the end of surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Boali hospital
Full name of responsible person
Mahdi Khalili
Street address
Bouali Hospital, after Imam Hossein Square, Damavand Street, Tehran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Arash Azizi
Street address
9th Neyestan, Pasdaran, Tehran
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Province
Tehran
Postal code
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Fax
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khalilimahdi67@gmail.com
Web page address
http://dental.iautmu.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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

Islamic Azad University

Full name of responsible person

Mahdi Khalili

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Oral and Maxillofacial Surgery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Resident

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparison of the effect of Apotel and Magnesium Sulfate on pain and dose of Pethidine in patients with maxillofacial surgery

When the data will become available and for how long

6 months after publication of thesis

To whom data/document is available

Oral and Maxillofacial Surgeons, Plastic Surgeons and ENT Surgeons

Under which criteria data/document could be used

The data is fully available to individuals to perform the desired analysis

From where data/document is obtainable

To receive the Thesis , refer to the research site of Azad University at https://ris.iau.ac.ir/

What processes are involved for a request to access

data/document

Registration in the research site of Azad University

Comments