

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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)

##### Phone

+98 21 2268 6549

##### Email address

khalilimahdi67@gmail.com

##### 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. Andarzgo 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.

##### City

Tehran

##### Province

Tehran

##### Postal code

1711734365

##### Phone

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##### Email

boali.hospital96@gmail.com

## 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

##### City

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##### Province

Tehran

##### Postal code

1946853314

##### Phone

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##### Fax

##### Email

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**  
Unite 20, No 2/1, Yaghout Buil, Yaghout Alley, Hoseini Alley, Saba Blvd, Andarzgou St, Tehran  
**City**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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1933865311  
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khalilimahdi67@gmail.com

## 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**