

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The evaluation of pre-operative Clonidine versus Ondansetron prescription for control of pain, nausea & vomiting after Orthognathic surgery.

#### Protocol summary

##### Summary

objective: The aim of this study was to compare the effect of ondansetron and clonidine for pain, nausea and vomiting after orthosurgery. Study type: Randomized clinical trial. Inclusion criteria: All adult patients with ASA class I, II, age range between 18 and 40 years with jaw deformity Exclusion criteria: Patients who had experience of previous Ponv, nausea and vomiting in last 24 hours Patients known to be sensitive to clonidine and ondansetron Patients with history of low blood pressure and bradycardia Sample size: 40 patients (20 in each group) The main intervention: Intervention 1: Prescription of ondansetron (8 mg) in form of oral tablets that have been dissolved in 20 ml of water (as intervention) one hour before general anesthesia of orthosurgery Intervention 2: Prescription of clonidine (150 µg) in form of oral tablets that have been dissolved in 20 ml of water (as intervention) one hour before general anesthesia of orthosurgery Underlying variables: age, BMI, gender The main measurable outcomes: pain, nausea, vomiting immediately and up to first 24 hours after surgery. study time: 8 month

#### General information

##### Acronym

Clonidine versus Ondansetron in Orthognathic surgery.

##### IRCT registration information

IRCT registration number: **IRCT2017012922697N2**  
Registration date: **2017-05-01, 1396/02/11**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-01, 1396/02/11

#### Registrant information

##### Name

Sahand Samiee rad

##### Name of organization / entity

mashhad dental school,oral and maxillofacial department

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3883 7289

##### Email address

samieerads@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chanscellor for research Mashhad university of medical sciences. Oral and maxillofacial disease research center

#### Expected recruitment start date

2017-04-04, 1396/01/15

#### Expected recruitment end date

2017-08-23, 1396/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The evaluation of pre-operative Clonidine versus Ondansetron prescription for control of pain, nausea & vomiting after Orthognathic surgery.

#### Public title

the evaluation of Clonidine versus Ondansetron for control of pain, nausea & vomiting after Orthognathic surgery.

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: All adult patients with ASA class I, II, age range between 18 and 40 years and BMI less than 30 kg per square meter, with jaw deformity and applicable for orthosurgery that referred to Mashhad dental school. Exclusion criteria: Patients with ASA III class and more. Patients with history of nausea in moving vehicles (Motion sickness) Patients who had experience of previous Ponv, nausea and vomiting in last 24 hours Patients with upper gastrointestinal disorders such as peptic ulcer disease, re flux, pyloric stenosis Patients with history of drug abuse and addiction Patients known to be sensitive to clonidine and ondansetron Patients with history of low blood pressure and bradycardia Patients who need to be care in ICU after surgery. Patients who not wish to continue participation in the program, for any reason.

## 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: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

As the effectiveness of clonidine or ondansetron in comparison with placebo for pain and PONV in surgical field is proved in other clinical trial studies; we decided to not have placebo in this study. Furthermore, the surgeon and anesthesiologist were aware of the drug types in order to prevent the peri and post operative complications; but the student who will record data and analyzing committee of information was blind. the patients were aware of the study interventions because of consent letter. Simple randomization ( Random number table) will be used in this study.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics committee of Mashhad dental school of Mashhad university of medical sciences,

#### Street address

Ghoreishi building, Daneshgah avenue

#### City

Mashhad

#### Postal code

#### Approval date

2016-12-18, 1395/09/28

#### Ethics committee reference number

IR.mums.sd.REC.1394.176

## Health conditions studied

### 1

#### Description of health condition studied

pain after orthosurgery

#### ICD-10 code

M25.5

#### ICD-10 code description

Pain in joint

### 2

#### Description of health condition studied

nausea and vomiting after orthosurgery

#### ICD-10 code

F50.5

#### ICD-10 code description

Vomiting associated with other psychological disturbances

### 3

#### Description of health condition studied

Jaw deformity

#### ICD-10 code

K07.9

#### ICD-10 code description

Dentofacial anomaly, unspecified

## Primary outcomes

### 1

#### Description

amount of pain

#### Timepoint

1,3,6,12,24 hours after surgery.

#### Method of measurement

VAS

### 2

#### Description

nausea and vomiting amount after surgery

#### Timepoint

1,3,6,12,24 hours after surgery.

#### Method of measurement

yes or no / dose of rescue anti emetic drug

## Secondary outcomes

### 1

#### Description

bradycardia

#### Timepoint

1,3,6,12,24 hours after surgery

#### Method of measurement

clinical observation

### 2

#### Description

blood pressure

#### Timepoint

1,3,6,12,24 hours after surgery

#### Method of measurement

clinical observation

## Intervention groups

### 1

#### Description

Intervention 1: Prescription of ondansetron (8 mg) (150 µg) in form of oral tablets that have been dissolved in 20 ml of water (as intervention) one hour before general anesthesia of orthosurgery

#### Category

Treatment - Drugs

### 2

#### Description

Intervention 2: Prescription of clonidine (150 µg) in form of oral tablets that have been dissolved in 20 ml of water (as intervention) one hour before general anesthesia of orthosurgery

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Oral and maxillofacial surgery department, Mashhad dental school

##### Full name of responsible person

Dr sahand samiee rad

##### Street address

Mashhad dental school, Vakil abad boulevard

##### City

Mashhad

### 2

#### Recruitment center

##### Name of recruitment center

Oral and maxillofacial surgery department of

Mashhad Qaem hospital

##### Full name of responsible person

Dr sahand samiee rad

##### Street address

Mashhad Qaem hospital, Ahmadabad boulevard

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research Mashhad university of medical sciences

##### Full name of responsible person

Dr Saeed Eslami

##### Street address

Ghoreishi building, Daneshgah avenue

##### City

Mashhad

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research Mashhad university of medical sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

oral and maxillofacial surgery department ,Mashhad dental school

##### Full name of responsible person

Dr Majid Eshghpour

##### Position

associate professor

##### Other areas of specialty/work

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## Person responsible for scientific inquiries

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Assistant prof

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## Person responsible for updating data

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Mashhad dental school

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Mohsen gholizadeh  
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Gholizadehm911@mums.ac.ir  
**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*