

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Phentolamine mesylate effect on duration of soft tissue local anesthesia and incidence of soft tissue trauma after mandibular injection in children in 4-6 years of age

#### Protocol summary

##### Summary

Phentolamine mesylate(PM) is antagonist of epinephrine and reduces duration of numbness of soft tissue after injection of local anesthesia. We evaluate the phentolamine mesylate effect on reversal time of normal sensation and trauma to the soft tissue after mandibular block injection in patient of 4-6 years of age. In this randomized double blind controled clinical trial 54 pediatric patients have been devided in two groups and after describing the process of this study to their parents(approved by medical sciences), in group 1 in the first visit, 30 minutes after local anesthesia injection, PM has been injected; in the second visit in this group patients receive local anesthesia injection without PM injection. In contrast the group 2 in the first visit receive a control injection(sham injection in which a needle does not penetrate the tissue) and in the second visit receive PM after local anesthesia. We evaluate reversal time of normal sensation of soft tissue every 15 minutes by soft tapping with index finger and also we assess the vital sign, incidence of trauma to soft tissue for 3-5 hours and patients have been followed for at least 48 hours.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201102285934N1**  
Registration date: **2012-05-17, 1391/02/28**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-05-17, 1391/02/28

##### Registrant information

##### Name

Mahdi Babaei

##### Name of organization / entity

Isfahan University of Medical Sciences-Dentistry college

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1788 3314

##### Email address

babaei@edc.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2011-04-09, 1390/01/20

##### Expected recruitment end date

2012-06-04, 1391/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Phentolamine mesylate effect on duration of soft tissue local anesthesia and incidence of soft tissue trauma after mandibular injection in children in 4-6 years of age

##### Public title

Phentolamine mesylate effect on duration of soft tissue local anesthesia and incidence of soft tissue trauma after local anesthesia

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: systematically healthy children who require routine dental treatment without allergies or intolerance to anesthetics, epinephrine, sulfites patient that requires bilateral dental procedure except extraction(2%lidocaine with 1/80000 epinephrine) andhaving weight equal or greater than 15kg. Exclusion criteria: patient requires more than 1 cartridge of lidocaine with 1/80000 epinephrine or another local anesthetic, sedation, lesser than 15kg and younger than 4 years of age.

#### Age

From **4 years** old to **6 years** old

#### Gender

Both

#### Phase

0

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **54**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Crossover

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan university of medical sciences

##### Street address

Isfahan university of medical sciences-Isfahan

##### City

Isfahan

##### Postal code

8174673461

#### Approval date

2011-03-12, 1389/12/21

#### Ethics committee reference number

390348

## Health conditions studied

### 1

#### Description of health condition studied

The effectiveness of phentolamine mesylate on the adverse effect of local anesthesia

#### ICD-10 code

Y48.3

#### ICD-10 code description

Local anaesthetics

## Primary outcomes

### 1

#### Description

The effectiveness of phentolamine mesylate on the reduction of reversal time of numbness of soft tissue

#### Timepoint

15 minutes

#### Method of measurement

A soft tapping by index finger to the trained children

### 2

#### Description

Trauma to soft tissue

#### Timepoint

Every 30 minutes

#### Method of measurement

Inspection

## Secondary outcomes

### 1

#### Description

The probability of change in the blood pressure

#### Timepoint

Every 30 minutes

#### Method of measurement

Digital sphygmomanometer

## Intervention groups

### 1

#### Description

Injection of phentolamine mesylate for pediatrics who weighted 15 kg or more and less than 30 kg receive one-half cartridge of anesthetics. Those weighing 30 kg or more received whole cartridge- Phentolamine injection perform 30 minutes after injection of local anesthesia- Trade name of drug is Oraverse

#### Category

Treatment - Drugs

### 2

#### Description

In control group, we apply the sham injection (needle does not penetrate the tissue) in the same side that local anesthesia has been injected.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The pediatric department, Faculty of dentistry,  
Isfahan University of Medical Sciences

##### Full name of responsible person

Dr. Nosrat Nourbakhsh, Assistant professor

##### Street address

plate 112-2th floor- 5th alley-Jaber street-Mardavij  
street-Isfahan

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Full name of responsible person

Mr.Tavangar

##### Street address

Dentistry college, Isfahan University of Medical  
Sciences

##### City

Isfahan

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Isfahan 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

Dentistry college, Isfahan University of Medical  
Sciences

##### Full name of responsible person

Dr. Mahdi Babaei

##### Position

MD, Postgraduate student

##### Other areas of specialty/work

##### Street address

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Assistant professor.department of pediatric dentistry,  
Isfahan University of Medical Sciences

##### Full name of responsible person

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## Person responsible for updating data

#### Contact

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Dentistry college, Isfahan University of Medical  
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##### Full name of responsible person

Dr. Mahdi Babaei

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MD, Postgraduate student

##### Other areas of specialty/work

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##### 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*