

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 an antagonist of epinephrine and reduces the 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 patients of 4-6 years of age. In this randomized double-blind controlled clinical trial 54 pediatric patients have been divided into 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 receives a control injection (sham injection in which a needle does not penetrate the tissue) and in the second visit receives PM after local anesthesia. We evaluate reversal time of normal sensation of soft tissue every 15 minutes by soft tapping with the 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

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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 lidocain 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mr.Tavangar

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

Dr. Mahdi Babaei

Position

MD, Postgraduate student

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Person responsible for scientific inquiries

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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