

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of Hydralazine on duration of soft tissue local anesthesia following dental treatment

Protocol summary

Summary

Hydralazine HCl is antagonist of epinephrine. We evaluate the Hydralazine HCl effect on reversal time of normal sensation and trauma to the soft tissue after mandibular block injection in patient of 18-80 years of age. In this randomized single blind controlled clinical trial 50 patients have been divided in two groups and the process of this study described to them (approved by medical sciences). On completion of the dental treatment, patients randomly received a Hydralazine HCl or a sham injection (sham injection in which a needle does not penetrate the tissue) in the same site as the local anesthetic injection. 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: **IRCT201312202877N2**

Registration date: **2014-02-08, 1392/11/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-08, 1392/11/19

Registrant information

Name

Omid Fakheran

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1661 9472

Email address

fakheran@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Isfahan University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2014-06-01, 1393/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Hydralazine on duration of soft tissue local anesthesia following dental treatment

Public title

Effect of Hydralazine on duration of soft tissue local anesthesia following dental treatment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Male or female greater than or equal to 18 years; Sufficiently healthy, as determined by the Investigator, to receive routine dental care; Requires one or two cartridges of local anesthesia administered by inferior alveolar nerve block techniques; Understands and gives written informed consent; Can communicate with the Investigator and study staff, and can understand and comply with the requirements of the protocol
Exclusion Criteria: History or presence of any condition that contraindicates routine dental care; Concurrent

conditions: any incapacitating medical condition (e.g. unstable angina, uncontrolled cardiac arrhythmias, uncontrolled hypertension, uncontrolled hyperthyroidism); significant infection or inflammatory process of the oral cavity; Concomitant medications: use of an opioid or opioid-like analgesic (e.g. codeine, tramadol, pentazocine) within 48 hours prior to administration of anesthetic; Allergy or intolerance to lidocaine, articaine, prilocaine, mepivacaine, epinephrine, levonordefrin, sulfites, phentolamine, or topical benzocaine; Any condition which, in the opinion of the Investigator, increases the risk to the subject of participating in this study or decreases the likelihood of compliance with the protocol

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Street, Isfahan, Iran, Isfahan University of Medical Sciences

City

Isfahan

Postal code

8174673461

Approval date

2010-12-08, 1389/09/17

Ethics committee reference number

288240

Health conditions studied**1****Description of health condition studied**

The effectiveness of Hydralazine HCl on the adverse effect of local anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes**1****Description**

Soft tissue local anesthesia

Timepoint

Just one day

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: completion of the dental treatment, patients randomly received a Sham injection in the same site as the local anesthetic injection

Category

Treatment - Drugs

2**Description**

Intervention group: completion of the dental treatment, patients randomly received a Hydralazine HCl injection in the same site as the local anesthetic injection 4 mg/ml Hydralazine HCl injection, (Rubio , Spain)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan Dental School, Isfahan University of Medical Sciences

Full name of responsible person

Omid Fakheran

Street address

226, Apadana Street, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Isfahan University of Medical Sciences

Full name of responsible person

Omid Fakheran Esfahani

Street address

Hezar Jarib Street, Isfahan, Iran, Isfahan University of Medical Sciences, Vice Chancellor for Research

City

Isfahan

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 of 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**

Isfahan University of Medical Sciences

Full name of responsible person

Omid Fakheran

Position

Periodontics Resident

Other areas of specialty/work**Street address**

226, Aftab alley, Apadana Street, Isfahan, Iran

City

Isfahan

Postal code

8165876763

Phone

+98 31 1661 9472

Fax**Email**

fakheran@dnt.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Omid Fakheran

Position

Periodontics Resident

Other areas of specialty/work**Street address**

Hezar Jarib Street, Isfahan, Iran, Isfahan University of Medical Sciences

City

Isfahan

Postal code

8174673461

Phone

+98 31 1661 9472

Fax

+98 31 1224 0262

Email

fakheran@dnt.mui.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Omid Fakheran

Position

Periodontics Resident

Other areas of specialty/work**Street address**

Hezar Jarib Street, Isfahan, Iran, Isfahan University of Medical Sciences

City

Isfahan

Postal code

8174673461

Phone

+98 31 1661 9472

Fax**Email**

fakheran@dnt.mui.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