

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Pressure Massage and Topical Gel on Pain During Inferior Alveolar Nerve Block and Maxillary Anterior Injections. A prospective, randomized, double-blind, clinical trial study.

Protocol summary

Summary

Aim: This study aimed to evaluate the efficacy of topical pressure massage and anesthetic gel on pain of dental injections. Design: In this double-blind, prospective, randomized clinical trial, eighty healthy volunteers will be participated. Methods: All the patients who have including criteria and have a mandibular premolar/molar or a maxillary anterior tooth with the diagnosis of normal pulp, reversible pulpitis or asymptomatic irreversible pulpitis will receive an injection in one of the following groups according to the random number table: 1. Group TPMB: Topical pressure and massage with an Inferior alveolar nerve block (IANB) 2. Group TGB: Topical gel of 20% Benzocain (Master-Dent, Monroe, NC) with IANB 3. Group TPMI: Topical pressure and massage with a maxillary anterior infiltration (MAI) 4. Group TGI: Topical gel with a MAI All the injections will be performed using an aspirating syringes containing 1.8 ml of lidocaine with 1:80000 epinephrine (2%Persocaine_E; Darupakhsh, Tehran, Iran) and 28-gauge needles by a single operator. Immediately after the injection, patients will be asked to record the amount of pain they felt during needle penetration and injection using visual analog scal(VAS) form. Only the first injection will be subjected to the evaluation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111916845N5**
Registration date: **2015-12-11, 1394/09/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-11, 1394/09/20

Registrant information

Name

Nahid Akhlaghi

Name of organization / entity

Tehran Dental Branch Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 21 2201 1751

Email address

n_akhlaghi@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2015-09-20, 1394/06/29

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Pressure Massage and Topical Gel on Pain During Inferior Alveolar Nerve Block and Maxillary Anterior Injections. A prospective, randomized, double-blind, clinical trial study.

Public title

Efficacy of Pressure Massage and Topical Gel on Pain During Intra Oral Injections

Purpose

Prevention

Inclusion/Exclusion criteria
Patients ranged 18-65 years old; No systemic disease; Non pregnant or breast feeding; A mandibular premolar/molar or a maxillary anterior tooth with the diagnosis of normal pulp, reversible pulpitis or asymptomatic irreversible pulpitis (Heft Parker visual analogue scale ≤ 54); Need dental treatment; Not taking analgesics, sedative or anti-anxiety medication during the last 24 hours; No intra oral injection at the treatment area during the last 24 hours

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
ClinicalTrials.gov

Secondary trial Id
NCT02601924

Registration date
1394-08-23, 777/01-1304

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Jomhuri Blvd

City
Kerman

Postal code

Approval date
2015-07-13, 1394/04/22

Ethics committee reference number
ir.kum.1394.215

Health conditions studied

1

Description of health condition studied
reversible/Irreversible pulpitis

ICD-10 code
K04

ICD-10 code description
Diseases of pulp and periapical tissues

Primary outcomes

1

Description
Pain during dental injection

Timepoint
2 minutes

Method of measurement
Pain rate using Visual Analog Scale(VAS) form

Secondary outcomes

empty

Intervention groups

1

Description
Topical Anesthetic Gel for Inferior Alveolar Nerve Block injection

Category
Prevention

2

Description
Topical Anesthetic Gel Maxillary Anterior Infiltration

Category
Prevention

3

Description
Topical Pressure Massage Inferior Alveolar Nerve Block injection

Category
Prevention

4

Description
Topical Pressure Massage Maxillary Anterior Infiltration

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Akhlaghi's Dental Clinic

Full name of responsible person

Nahid Mohammadzadeh Akhlaghi

Street address

5th floor, no 7, Golshahr Blvd, Africa Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhty

Street address

Jomhori Blvd

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Dental Branch, Tehran Azad University

Full name of responsible person

Nahid Mohammadzadeh Akhlaghi

Position

Associate Professor, DDS/MDS

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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