

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Eutectic Mixture of Lidocaine and Prilocain (EMLA) anesthetic gel on pain during Probing in Patients With chronic Periodontists.

Protocol summary

Summary

Aim: Probing is the only reliable method for the detection of periodontal disease yet is painful. EMLA anesthetic gel can be used for decreasing pain during probing. The aim of this study was to evaluate the effect of EMLA anesthetic gel on pain during Probing in patients with chronic periodontists who were referred to the Department of Periodontal, dental branch, Islamic Azad University. Method: This clinical, double-blind, Split Mouth study was performed on 20 eligible patients. All existing teeth in two quadrant were randomized assigned as anesthetic (test) or placebo (control) group and probing was done at 6 site per teeth. Pain was measured using VAS (10 cm) before and 30 second after application of gel and data was recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409143720N4**

Registration date: **2015-02-28, 1393/12/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-28, 1393/12/09

Registrant information

Name

Roya Shariatmadarahmadi

Name of organization / entity

Department of periodontology, Dental branch, Islamic Azad University

Country

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Eutectic Mixture of Lidocaine and Prilocain (EMLA) anesthetic gel on pain during Probing in Patients With chronic Periodontists.

Public title

A randomized double-blind placebo controlled clinical trial of the effect of Eutectic Mixture of Lidocaine and Prilocain (EMLA) anesthetic gel on pain during Probing in Patients With chronic Periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were: patients with chronic periodontists with PD ≥ 4 mm and CAL ≥ 3 ; patients needed to have a minimum of one incisors, one canine, one premolar, and one molar in two quadrants; patients with no periodontal therapy in the previous 6 months; and a signed informed consent form exclusion criteria:

those requiring prophylactic antibiotics before periodontal probing; those suffering from any psychiatric disorders or with chronic pain problems; those with coagulation disorders or on anti coagulation therapy; female patients that were pregnant or lactating; patients with congenital or idiopathic met- hemoglobinemia or those receiving treatment with methemoglobin-inducing agents; those reporting allergies to dental anesthetics; those taking non-steroidal anti-inflammatory drugs in the 3 days before participation in the study; patients having acute periodontal pain, pulpitis, abscesses, or other acute infections.

Age

No age limit

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)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

randomisation was performed by coin.

Secondary Ids

empty

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

Ethics committee of Islamic Azad University- dental branch

Street address

no:4 - 10th neyestan- pasdaran st.-Tehran - Iran

City

Tehran

Postal code**Approval date**

2014-11-12, 1393/08/21

Ethics committee reference number

24311

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

Periodontitis

ICD-10 code

ko5.3

ICD-10 code description

Periodontitis

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

pain during probing

Timepoint

before intervention/30-45 seconds after intervention

Method of measurement

Visual analog pain with ruler (VAS)

Secondary outcomes

empty

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

Intervention group: EMLA gel 2.5% (Eutectic Mixture of Lidocain Prilocain)(Made by Pharmaceutical Laboratory of Hakim Co,Tehran- Iran .

Category

Treatment - Drugs

2**Description**

"Control group":Placebo gel was prepared in the same manner but without the active drug in it(Made by Pharmaceutical Laboratory of Hakim Co,Tehran- Iran .

Category

Placebo

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

Islamic Azad University of Tehran, Dental Branch

Full name of responsible person

Dr.Roya ShariatmadarAhmadi

Street address

No:4, 10th Neyestan, Pasdaran St., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research Council of Dental Branch Islamic
Azad University of Tehran

Full name of responsible person

Dr Azizi

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No:4,,10th Neiyestan, pasdaran St., Tehran, Iran

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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

Deputy of Research Council of Dental Branch Islamic
Azad University of Tehran

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**

Islamic Azad University of Tehran-Dental Branch

Full name of responsible person

Dr Roya Shariatmadarahmadi

Position

Assistant professor

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

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Person responsible for scientific inquiries

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Position

periodontist

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

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Web page address

Person responsible for updating data

Contact

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