Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 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

Iran (Islamic Republic of)

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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, pulpits, 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 neiystan- 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 intervetion/30-45 seconds aftherintervention

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

City
Tehran

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

Street address
No:4,,10th Neiystan, 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
Assisstant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University of Tehran- Dental Branch

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Dr.Roya Shariatmadarahmadi

Position
periodontist

Other areas of specialty/work

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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