

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Evaluation of ice therapy as a pretreatment on reduction of injection pain and bleeding during periodontal surgery of maxilla after administration of prilocaine as a local anesthesia.

Protocol summary

Summary

The aim of this study was to determine the effect of pretreatment with ice on reducing pain during injection and bleeding during periodontal surgery after administration of prilocaine(without vasoconstrictors) as a local anesthetic in maxillary periodontal surgery. Inclusion criteria: no history of systemic diseases especially hemorrhagic disorders, Women must not be pregnant, Patients must not have fear of surgery, Patient must not have used acetaminophen, phenastin, naproxen, or ibuprofen Exclusion criteria: people with mental retardation, children, patients that have used analgesics. 80 patients aged 12 to 70 were randomly chosen and divided into two groups: the control and the study group. The indication for performing the periodontal surgery in the maxilla is the same in both groups. Both have been matched for interfering factors like sex and age. The experimental group are pretreated with ice packs on the injection site for 2 minutes, whereas the control group is not pretreated with ice. After the surgery, the patient's pain is assessed using the Visual analog scale analysis in which the patient reports his or her pain by themselves. This scale is graded from 0 to 5, where 0 means no pain and 5 means severe pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502077128N5**

Registration date: **2015-03-26, 1394/01/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-03-26, 1394/01/06

Registrant information

Name

Adileh Shirmohammadi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-04-01, 1394/01/12

Expected recruitment end date

2015-10-01, 1394/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of ice therapy as a pretreatment on reduction of injection pain and bleeding during periodontal surgery of maxilla after administration of prilocaine as a local anesthesia.

Public title

Evaluation of ice therapy as a pretreatment on reduction of injection pain and bleeding during periodontal surgery of maxilla after administration of prilocaine as a local anesthesia.

Purpose

Treatment

Inclusion/Exclusion criteria
inclusion criteria:no history of systemic diseases
especially hemorrhagic disorders.women must not be
pregnant.patients must not have fear of surgery.patient
must not have used acetaminophen with
phenastin,naproxen,ibuprofen, Exclusion criteria:people
with mental retardation, children,patient that have used
analgesics.

Age
From **12 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Dentistry Faculty Of Tabriz

Street address

Tabriz Faculty Of Dentistry

City

Tabriz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

9399

Health conditions studied

1

Description of health condition studied

periodontal disease

ICD-10 code

k05.6

ICD-10 code description

Periodontal disease, unspecified

Primary outcomes

1

Description

pain

Timepoint

before injection

Method of measurement

patient reaction and expression

Secondary outcomes

empty

Intervention groups

1

Description

precooling with ice before injection

Category

N/A

2

Description

No action

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry Faculty Of Tabriz

Full name of responsible person

Dr Adileh Shirmohamadi

Street address

Tabriz Faculty Of Dentistry

City

Tabriz

2

Recruitment center

Name of recruitment center

Dental and Periodontal Research Center

Full name of responsible person

Dr Reza Pourabbas

Street address

Tabriz Faculty Of Dentistry

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dentistry Faculty Of Tabriz

Full name of responsible person

Dr Adileh Shirmohamadi

Street address

Tabriz Faculty Of Dentistry

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dentistry Faculty Of Tabriz

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Dental and Periodontal Research Center

Full name of responsible person

Dr Reza Pourabbas

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Tabriz Faculty Of Dentistry

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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

Dental and Periodontal Research Center

Proportion provided by this source

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 Faculty Of Tabriz

Full name of responsible person

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Position

Undergraduate student

Other areas of specialty/work

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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