

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of vibratory stimulation and cooling and topical anesthesia efficacy on pain during needle insertion and local anesthesia injection in anterior maxilla: a randomized clinical trial

Protocol summary

Study aim

Evaluation of vibratory stimulation and cooling and topical anesthesia gel efficacy on pain during needle insertion and local anesthesia injection in anterior maxilla

Design

Parallel group randomised trial, single blind, phase 2-3, 200 patient. Randomisation is done with eight blocks.

Settings and conduct

The research site is in the endodontics department of the School of Dentistry of Isfahan University of Medical Sciences. In this study, the effect of vibration, cold and anesthesia gel before injection in the anterior part of the maxilla, on the amount of pain during needle insertion and injection of anesthetic is investigated. No intervention is performed before injection of anesthesia in the control group. This study is performed in a single-blind manner. One person performs all the injections, knowing how to assign individuals to the four intervention groups. The other person will not know what group everyone is in and will receive a pain score from the patients. The person for whom blinding is performed in this study is responsible for evaluating patients' pain after the intervention.

Participants/Inclusion and exclusion criteria

Patient in the ASA I classification range in age between 18 and 60 years. Teeth that require root canal treatment in the anterior maxilla with asymptomatic irreversible pulpitis, normal periapical without periodontal disease.

Intervention groups

Before injection of anesthesia ,In first group, a cold spray-soaked ear cleaner is placed for one minute. In second group, a one-minute vibrating device is placed. In the third group, topical gel is placed for one minute. In the fourth group (control group) before injection no intervention is used.

Main outcome variables

If vibration or cold are as effective as topical gel in reducing pain when the anesthetic is injected, vibration or cold can be used before injection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191114045442N2**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **prospective**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

Registration date

2021-06-19, 1400/03/29

Registrant information

Name

Neda Shekarchizade esfahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3629 5052

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neda_shekarchizade@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vibratory stimulation and cooling and topical anesthesia efficacy on pain during needle insertion and local anesthesia injection in anterior maxilla: a randomized clinical trial

Public title

Evaluation of vibratory stimulation efficacy on pain during needle insertion and local anesthesia injection in anterior maxilla

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

(ASA I) American Society of Anesthesiologists I Teeth with anterior maxillary root canal treatment with asymptomatic irreversible pulpitis, and normal periapical No periodontal disease Teeth adjacent to the target tooth should not have any infection or swelling Have not taken medications that change the perception of pain (such as painkillers, opioids, antidepressants, anti-anxiety drugs, alcohol) in the last 2 weeks No addiction Do not have pain or dental infection

Exclusion criteria:

Patients who do not want to continue cooperating during the tests

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization is based on block randomization using eight blocks. 25 blocks of eight quadrants will be selected randomly adopting random number table method. Patients under study will be assigned to one of two groups of intervention and control groups based on the order of blocks selection.

Blinding (investigator's opinion)

Single blinded

Blinding description

One person will do all the injections, which will show how people are assigned to the four intervention groups, and the other person will not know what group everyone is in, and will receive pain scores from patients. The person for whom blinding is performed in this study is responsible for evaluating patients' pain after the intervention.

Placebo

Not 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

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

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isfahan

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Isfahan

Postal code

81744-73461

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.833

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

Asymptomatic irreversible pulpitis, normal periapical

ICD-10 code

pulpitis

ICD-10 code description

K04.0

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

Pain

Timepoint

Pain when inserting a needle and pain during injecting of anesthesia solution in the anterior region of the maxilla

Method of measurement

Heft-Parker visual analog scale (VAS)

Secondary outcomes

empty

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

Intervention group 1: Before injection, a cold spray-soaked ear cleaner is placed in the buccal vestibule area for one minute. Intervention group 2: Before injection, a vibrating device is placed in the area of the buccal vestibule for one minute. Intervention group 3: Before injection, a topical gel is placed in the buccal vestibule area for one minute.

Category

Prevention

2**Description**

Control group: without any intervention (cold-spray, vibration and topical gel), local anesthetic injection is performed with infiltration technique in the buccal vestibule area of the anterior teeth.

Category

N/A

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

Department of Endodontics, Dental School, Isfahan

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Neda Shekarchizade

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

All data can be shared after unidentified individuals.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

additional supporting information/documents will be
shared only for people working in academic institutions

Under which criteria data/document could be used

Any analysis of the data is allowed.

From where data/document is obtainable

Dr Neda Shekarchizade Email:

Neda_shekarchizade@yahoo.com

What processes are involved for a request to access data/document

It takes about a month for the documentation to reach
the applicant.

Comments