

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Study of the effect of Vibration on Needle Penetration and Injection Pain Following Maxillary Anterior Infiltrations and Inferior Alveolar Nerve Blocks Anesthesia in Patients Who Need Two Visit Root Canal Therapy: A Cross Over Study

Protocol summary

Study aim

Comparison of patient's self-reported pain in two injection methods with dental vibrate and traditional method(without dental vibrate) during needle penetration and local anesthesia injection

Design

A concealed, randomized using random number table, sham controlled clinical trial with a cross over design of 48 patients

Settings and conduct

Endodontic Department of Dental school of Shahid Beheshti University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria ; 12-65 years old systemically healthy patients who need two visit treatment for Root Canal therapy (RCT) in the maxilla or mandible Exclusion criteria ; systemic diseases, allergy to Lidocaine or sulfites, using drug that affect the patient pain response (excessive alcohol consumption, narcotics, barbiturates), severe dental pain that needs emergency treatment.

Intervention groups

1. Anesthetic injection group(inferior alveolar nerve block or anterior maxillary infiltration) without vibration of dental vibrate 2. Anesthetic injection group(inferior alveolar nerve block or anterior maxillary infiltration) with vibration of dental vibrate

Main outcome variables

1. Needle penetration pain 2. Anesthetic injection pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150720023253N4**

Registration date: **2018-05-17, 1397/02/27**

Registration timing: **retrospective**

Last update: **2018-05-17, 1397/02/27**

Update count: **0**

Registration date

2018-05-17, 1397/02/27

Registrant information

Name

Nazanin Zargar

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 3075

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2018-09-01, 1397/06/10

Actual recruitment start date

2016-02-09, 1394/11/20

Actual recruitment end date

2016-07-19, 1395/04/29

Trial completion date

empty

Scientific title

Study of the effect of Vibration on Needle Penetration and Injection Pain Following Maxillary Anterior

Infiltrations and Inferior Alveolar Nerve Blocks Anesthesia in Patients Who Need Two Visit Root Canal Therapy: A Cross Over Study		School Of Dentistry, Shahid Beheshti University of Medical Sciences, Evin, Shahid Chamran highway, Tehran, Iran	
Public title	Effectiveness of Vibration on Needle Penetration Pain and Intra-Oral Local Anesthesia Injection	City	Tehran
Purpose	Supportive	Province	Tehran
Inclusion/Exclusion criteria		Postal code	1983963113
Inclusion criteria:	patients who have 12-65 years old. patients who are Systemically healthy. Patients who need two visit treatment for root canal therapy(RCT) in the maxilla or mandible	Approval date	2015-07-09, 1394/04/18
Exclusion criteria:	patients who have systemic diseases. patients who have allergy to Lidocaine or sulfites. patient who used medications that affect the patient' pain response(excessive alcohol consumption, narcotics, barbiturates) patients who have severe dental pain that needs emergency treatment.	Ethics committee reference number	IR.SBMU.RIDS.1394.110
Age	From 12 years old to 65 years old	Health conditions studied	
Gender	Both	1	
Phase	N/A	Description of health condition studied	
Groups that have been masked	No information	pain	
Sample size	Target sample size: 48 Actual sample size reached: 48	ICD-10 code	
Randomization (investigator's opinion)	Randomized	R52.9	
Randomization description	Simple randomization technique with table of random numbers will be used. For allocation concealment a nurse in department knew the code number of every patient and she informs it to clinician just before treatment.	ICD-10 code description	
Blinding (investigator's opinion)	Not blinded	Generalized pain NOS	
Blinding description		Primary outcomes	
Placebo	Not used	1	
Assignment	Crossover	Description	
Other design features		Needle insersion pain in infiltration anesthesia in anterior site of maxilla	
Secondary Ids	empty	Timepoint	
Ethics committees		During needle insersion	
1		Method of measurement	
Ethics committee		VAS	
Name of ethics committee	Ethics committee of Shahid Beheshti University of Medical Sciences, School Of Dentistry	2	
Street address		Description	
		Injection pain in infiltration anesthesia in anterior site of maxilla	
		Timepoint	
		During injection	
		Method of measurement	
		VAS	
		3	
		Description	
		Injection pain in inferior alveolar nerve block anesthesia in mandible	
		Timepoint	
		During injection	
		Method of measurement	
		VAS	
		4	
		Description	
		Needle insersion pain in inferior alveolar nerve block anesthesia in mandible	

Timepoint

During needle insertion

Method of measurement

VAS

Secondary outcomes

empty

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

Intervention group: Needle insertion and anesthesia injection with dental vibe that cause vibration in injection site

Category

Other

2**Description**

Control group : Needle insertion and anesthesia injection without dental vibe

Category

Other

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

Shahid Beheshti University Of Medical Sciences ,
Faculty Of Dentistry

Full name of responsible person

Dr nazanin zargar

Street address

Shahid Beheshti Dental School-Daneshjoo Boulevard-
Velenjak-Shahid Chamran high way-Tehran-Iran

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<http://www.dentistry.sbm.ac.ir>

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

Shahid Beheshti University Of Medical Sciences ,
Faculty Of Dentistry

Full name of responsible person

Dr Zarghi

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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

Shahid Beheshti University Of Medical Sciences , Faculty
Of Dentistry

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**

Shahid Beheshti University Of Medical Sciences ,
Faculty Of Dentistry

Full name of responsible person

Dr nazanin zargar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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