

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of auricular acupuncture on the success of inferior alveolar nerve block among patients with irreversible pulpitis in mandibular teeth

Protocol summary

Study aim

The effect of auricular acupuncture on the success of inferior alveolar nerve block in mandibular teeth with irreversible pulpitis

Design

Randomized, double blind trial with control group and parallel group design

Settings and conduct

In the experimental group, ASP acupuncture needle will be inserted on acupuncture point for dental pain control and sticking plaster will be used on that. In control group a real puncture of needle will not happen and only sticking plaster will be used on points. 10 minutes after acupuncture, an endodontist will administer IANB injection in 60 seconds, based on a standard IANB method. After 15 minutes patients who will not report lip numbness will be excluded from study because this is a failed IANB. If they report lip numbness, endodontic procedure will be started. The patients will be instructed to report pain experienced during cavity preparation of dentin, exposure of pulp chamber and inserting initial file. Whenever a patient reports severe pain (>30 mm on VAS of 100 mm), a supplementary injection will be performed if they ask and that IANB will be considered unsuccessful. At the end of the endodontics procedure, the acupuncture's ASPs will be removed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have a mandibular molar with irreversible pulpitis, Between 18 and 65 years old.
Non-inclusion criteria: Pregnancy; Systemic disease; Using alcohol, drug or smoking; taking any corticosteroid, analgesic or antidepressant; sensitivity to lidocaine; periapical radiolucency.

Intervention groups

In the experimental group, ASP acupuncture needle will be inserted on acupuncture point for dental pain control and sticking plaster will be used on that. In control group a real puncture of needle will not happen and only sticking plaster will be used on points.

Main outcome variables

Mandibular anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181122041724N1**

Registration date: **2019-01-06, 1397/10/16**

Registration timing: **retrospective**

Last update: **2019-01-06, 1397/10/16**

Update count: **0**

Registration date

2019-01-06, 1397/10/16

Registrant information

Name

Ehsan Esnaashari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-08, 1397/09/17

Expected recruitment end date

2018-12-25, 1397/10/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of auricular acupuncture on the success of inferior alveolar nerve block among patients with irreversible pulpitis in mandibular teeth

Public title

The effect of auricular acupuncture on nerve block injection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have a mandibular molar with irreversible pulpitis . These teeth will be evaluated via an electric pulp test and a cold test Patients Between 18 and 65 years old Patients who agree to participate in this study

Exclusion criteria:

Pregnancy Systemic and mental disease Using alcohol, any drug and smoking taking any analgesic drugs in last 6 hours using any type of antidepressant medication such as TCA and SSRIs that could affect the perception of pain using any type of corticosteroid sensitivity to lidocaine patient's age under 18 and over 65 periapical radiolucency or even a widening of the periodontal ligament space in radiography patients who do not report lip numbness during 15 minute after injection

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the patients, 56 papers will be numbered 1 to 56, and the first 28 papers will be placed individually in a red sealed envelope; the remaining 28 will be placed individually in a blue sealed envelope. Each female participant will be instructed to select a red sealed envelope, and each male participant will be asked to select blue one. Upon opening the envelopes, based on the number (odd numbers for the auricular acupuncture group and even numbers for the control group), they will be assigned to 1 of the 2 corresponding groups. This ensures an equal number of male and female participants per group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical observer: An instructed person will apply

acupuncture, and a second investigator who is an endodontist administers IANB injection and endodontic procedure will be done. No one knows patients belong to which group , except who applies acupuncture so others are blind. Patient: In the acupuncture experimental group, the acupuncture points will be selected by acupuncture probe. An ASP acupuncture needle will be inserted at mentioned points on the side of the subjected tooth and sticking plaster will be used on that. In control group same points will be find by acupuncture probe but acupuncture needle will be inserted at other points which have no effect on dental pain and sticking plaster will be used on those points . At the end of the endodontics procedure , the acupuncture's ASPs and sticking plasters will be removed so patients will not understand the difference and they are blind. The person who evaluates the result: The same person who accomplish endodontic procedure (who is blind) and at last gives the result to the person who applies acupuncture (who is not blind) . Data analyzer: The person who analyzes data , will not know patients belong to which group and therefore he will be blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Central organizationn of Islamic Azad University

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No 9, Neyestan 9 ,Pasdaran Street

City

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Province

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Postal code

1946853314

Approval date

2018-04-22, 1397/02/02

Ethics committee reference number

IR.IAU.DENTAL.REC.1397.003

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

mandibular molar with irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Amount of pain reported by patient on 100 mm type of visual analog scale

Timepoint

during cavity preparation of dentin, exposure of pulp chamber and inserting initial file

Method of measurement

100 mm type of visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the acupuncture experimental group, the acupuncture point for dental pain control and pain control in mandible, and also Shen Men and Talamus points will be selected by acupuncture probe. An ASP acupuncture needle will be inserted at mentioned points on the side of the subjected tooth and sticking plaster will be used on that.

Category

Treatment - Devices

2

Description

Control group: In the Control group the same procedure will be mimiced . the acupuncture point for dental pain control and pain control in mandible, and also Shen Men and Talamus points will be selected by acupuncture probe but a real puncture of needle will not happen at mentioned points and only sticking plaster will be used on those points.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University of Tehran,Dental Branch

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Ehsan Esnaashari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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

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Full name of responsible person

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Other areas of specialty/work

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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