Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of using auricular acupuncture in reducing the onset time of lidocaine anesthesia in molars extraction

Protocol summary

Study aim

1.Assess ear acupuncture's impact on reducing lidocaine anesthesia onset during posterior mandibular tooth extraction. 2.Compare lidocaine anesthesia duration between intervention and control groups. 3.Evaluate post-surgery pain disparity between intervention and control groups at specified intervals 4.Compare anesthetic quantities used in intervention versus control groups 5.Examine acupuncture's role as supplementary anesthesia in post-surgery pain alleviation

Design

Two Period Cross Over Clinical Trial. Patients are examined in two periods and two periods, unblinded, randomized, block randomization using the Randomization.com

Settings and conduct

Bushehr University's dental clinic methodically selects patients, reviews medical history, obtains consent, uses ear acupuncture, and administers lidocaine anesthesia. Timing the onset of numbness, they perform surgery or extraction. Patients receive a post-surgery pain form. For subsequent extractions on the opposite side, acupuncture isn't used beforehand.

Participants/Inclusion and exclusion criteria

Entry criteria: healthy patients who need mandibular anesthesia. Those who have similar teeth in two opposite quadrants in the lower jaw that need to be extracted. People who do not have needle phobia. People who are not addicted. Exclusion criteria: All patients who need non-lidocaine anesthesia, those who have an infection at the place where the needles are inserted. Pregnant people. Presence of dental abscess, presence of large scars caused by jaw and face surgeries

Intervention groups

Intervention group: patients who receive ear acupuncture with lidocaine anesthesia Control group: patients who only receive lidocaine anesthesia.

Main outcome variables

1Anesthesia effect time 2Elapsed time until taking the first pain medication after dental surgery 3The amount of pain after surgery 4 Amount of anesthetic used 5 Complications of ear acupuncture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240109060660N1**
Registration date: **2024-01-15, 1402/10/25**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-15, 1402/10/25**
Update count: **0**

Registration date

2024-01-15, 1402/10/25

Registrant information

Name

Mehrnoosh Fathi alikordi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 3139

Email address

mehrnooshfathi8118@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-13, 1402/10/23

Expected recruitment end date

2024-02-29, 1402/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using auricular acupuncture in reducing the onset time of lidocaine anesthesia in molars extraction

Public title

Investigating the effect of using auricular acupuncture in reducing the onset time of lidocaine anesthesia in molars extraction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy patients who need mandibular anesthesia. Those Those who have similar teeth in two opposite quadrants in the lower jaw that need to be extracted. who do not have needle phobia. People who are not addicted.

Exclusion criteria:

All patients requiring non-lidocaine anesthesia. those with infection at the site of needle insertion. Pregnant women Presence of dental abscess presence of large scars caused by jaw and face surgeries

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

More than 1 sample in each individual

Number of samples in each individual: **2**

Tooth extraction or surgery using auricular acupuncture before anesthesia, tooth extraction or surgery without aurucular acupuncture

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization with a block size of 6 is used. A block randomization design will be generated using the free website below. (Seed: 188521504972600) https://www.sealedenvelope.com

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bushehr University of Medical Sciences

Street address

No. 1, 28th Alley, Vokala Ave., Iman shomali

City

Shiraz

Province

Fars

Postal code

7186645847

Approval date

2023-12-18, 1402/09/27

Ethics committee reference number

IR.BPUMS.REC.1402.223

Health conditions studied

1

Description of health condition studied

Investigating the effect of using ear acupuncture as adjunctive anesthesia in surgery or extraction of posterior mandibular teeth

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Investigating the effect of using ear acupuncture as an auxiliary anesthesia in surgery or extracting posterior mandibular teeth on pain after surgery.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anesthesia effect time

Timepoint

After the end of mandibular block anesthesia until lip tingling

Method of measurement

Using a stopwatch

Secondary outcomes

1

Description

The amount of pain after surgery

Timepoint

Immediately after the surgery, 6, 12, 24, 36 and 48

hours after the surgery and also between these intervals, there is pain in the face.

Method of measurement

Using the Defense and Veterans Pain Rating Scale

2

Description

Elapsed time until taking the first pain medication after dental surgery

Timepoint

After tooth extraction

Method of measurement

Patient self-reporting and hourly basis

3

Description

Amount of anesthetic used

Timepoint

During the tooth extraction process

Method of measurement

Based on the number of anesthetic carpools used

Intervention groups

1

Description

Intervention group: Using ear acupuncture before lidocaine anesthesia. Use of 0.16 x 8 mm Sujok acupuncture needles made of silver or steel. After 10 to 15 minutes, use ASP needles which are made of silver or steel.

Category

Treatment - Other

2

Description

Control group: Use of lidocaine anesthesia before tooth extraction.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bushehr University of Medical Sciences dental clinic

Full name of responsible person

Amrollah Rezaei

Street address

Kuy-e-Bandar، Moallem St

City

Bushehr

Province

Boushehr

Postal code

7518759577

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+98 77 3345 2227

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+98 77 3345 0235

Email

mehrnooshfathi8118@gmail.com

Web page address

http://bpums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Akram Farhadi

Street address

بوشهر ، بهمنی ، خیابان سلمان فارسی ، پردیس علوم پزشکی ، طبقه اول

City

Bushehr

Province

Boushehr

Postal code

7514633341

Phone

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Fax

+98 77 3345 2228

Email

Pkarshenasan@Yahoo.com

Web page address

https://rs.bpums.ac.ir/fa/index.aspx

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Mehrnoosh Fathi alikordi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No. 1, 28 Alley, Vokala Av.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

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Person responsible for updating data

Contact

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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