Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

عنوان طرح (انگلیسی) Comparison of posterior maxillary tooth extraction pain among opium abusers anesthetized with lidocaine VS Articaine: A randomized Clinical trial

Protocol summary

Study aim

If Articaine proves statistically and clinically superior to Lidocaine in controlling pain among patients, it will enhance treatment quality and reduce additional anesthetic use, leading to cost savings in dental practice and overall healthcare.

Design

A randomized, double-blind, controlled clinical trial with parallel groups conducted on 36 patients. Randomization was performed using SPSS software.

Settings and conduct

Eligible patients, after signing informed consent, are randomized into two groups using a random number table generated by SPSS 2022. To maintain blinding of the statistician, all patient data are coded and delivered to the analyst using random numerical identifiers. Patients are then referred, according to the randomization protocol, to a single dentist who performs all extractions. Pain intensity and anesthetic duration are assessed at 5 and 10 minutes after extraction, and vital signs (systolic BP, diastolic BP, SpO_2, heart rate) are measured 30 minutes post-extraction.

Participants/Inclusion and exclusion criteria

Inclusion: Age >18 years Moderate or severe opioid use disorder Exclusion: Surgical extraction First or third trimester pregnancy Uncontrolled diabetes or other uncontrolled systemic diseases Antihistamine use within 8 h or NSAID use within 6 h before visit Herpetic lesions Postmenopausal women History of radiotherapy or chemotherapy Bleeding disorders Abscess Periodontitis Severe periapical inflammation

Intervention groups

Intervention group: Local anesthesia with Articaine
Control group: Local anesthesia with Lidocaine

Main outcome variables

Pain intensity , Blood oxygen saturation (SpO_2), Diastolic blood pressure ,Systolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250917067281N1**
Registration date: **2026-05-18, 1405/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-18, 1405/02/28**
Update count: **0**

Registration date

2026-05-18, 1405/02/28

Registrant information

Name

Iman Tavakoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 080 2781

Email address

i.tavakolihosseini@ssu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-06-10, 1404/03/20

Expected recruitment end date

2027-02-19, 1405/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

(عنوان طرح (انگلیسی Comparison of posterior maxillary tooth extraction pain among opium abusers anesthetized with lidocaine VS Articaine: A randomized Clinical trial

Public title

Comparison of the Effect of Articaine and Lidocaine in Tooth Extraction of Opioid-Addicted Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants in both groups must be over 18 years of age, and only extraction of their posterior maxillary teeth—excluding third molars—will be performed for inclusion in the study. All individuals with moderate to severe opioid addiction, as determined by the DSM-5 questionnaire, are eligible for inclusion in the control group. Pregnant women may participate only if they are in the second trimester and possess medical consultation approval. If a patient presents with an abscess, drainage will be performed and, if antibiotic therapy is required, tooth extraction will be postponed until infection resolution. If the patient has periodontitis, extraction will be carried out only after appropriate antibiotic and periodontal therapy.

Exclusion criteria:

Patients with severe periapical inflammation—without abscess formation but with marked tenderness to percussion—will be excluded from the study. Patients with bleeding disorders will be excluded. Patients undergoing radiotherapy or chemotherapy will be excluded from the study. Postmenopausal women are excluded due to the naturally increased sensitivity to pain stimuli. Patients with herpetic lesions will not be included until complete healing has occurred. Patients whose tooth extraction requires surgical procedures, as well as those who have taken antihistamines within 8 hours or NSAIDs within 6 hours prior to the appointment, will be excluded. Patients requiring surgical tooth extraction will be excluded from the study. Additionally, those in the first or third trimester of pregnancy, patients with diabetes, and individuals with debilitating or uncontrolled systemic diseases will not be included.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method and Allocation Concealment Participants were assigned to two groups using simple randomization. The unit of randomization was the individual participant. The random sequence was generated using SPSS software version 22 (IBM Corp., Armonk, NY, USA), based on a random number table function. To ensure prevention of selection bias, allocation concealment was achieved using sequentially numbered, sealed opaque envelopes (SNOSE). Each envelope contained the allocation determined by the random sequence and was opened only after the participant’s enrollment and consent. The envelopes were identical, opaque, and sealed to prevent foreknowledge of group assignment, ensuring complete concealment until the moment of allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, to minimize bias, blinding is implemented at the levels of the patient, pain assessor, and statistical analyst. The study medications (2% lidocaine with 1:80,000 epinephrine and 4% articaine with 1:100,000 epinephrine) are withdrawn from their original cartridges by the treating dentist prior to the patient’s entry into the operatory and transferred into completely identical syringes devoid of any markings or labels. Each syringe is then labeled solely with a code, either “A” or “B.” As all syringes are prepared before the patient enters the treatment room and outside the operatory, patients do not observe the original cartridges or the type of anesthetic agent at any stage. Therefore, patient-level blinding is fully maintained. Blinding at the operator level is not feasible, as the treating dentist directly observes the syringe contents during preparation and must also carefully manage patients who use opioids. Consequently, the operator is aware of the type of anesthetic administered. Pain assessment at 5, 10, and 30 minutes following tooth extraction is performed by an independent assessor who is unaware of the injected anesthetic agent and the patient’s allocation group. The assessor records pain intensity using only the patient identification code and the Visual Analog Scale (VAS). The statistical analyst has access exclusively to coded data labeled “A” or “B” and is unaware of the actual drug identity or patient information. Unblinding is conducted solely by the principal investigator after completion of the statistical analysis. Accordingly, blinding is fully maintained at the levels of the patient, pain assessor, and statistical analyst until the conclusion of data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Sadoughi University of Dentistry
Street address
Yazd Province, Yazd, Dah-e-Fajr, W97M+8RF
City
Yazd
Province
Yazd
Postal code
8914881167
Approval date
2025-05-20, 1404/02/30
Ethics committee reference number
IR.SSU.DENTISTRY.REC.1404.014

Health conditions studied

1

Description of health condition studied
عنوان طرح (انگلیسی) Comparison of posterior maxillary tooth extraction pain among opium abusers anesthetized with lidocaine VS Articaine: A randomized Clinical trial
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain Assessment After Tooth Extraction Using the Visual Analog Scale (VAS)
Timepoint
At 5 and 10 minutes after tooth extraction
Method of measurement
Use of the Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Comparison of Vital Signs (Systolic Blood Pressure, Diastolic Blood Pressure, SpO_2, Heart Rate)
Timepoint
30 minutes after tooth extraction
Method of measurement
By means of a Pulse Oximeter

Intervention groups

1

Description
:::writingOne cartridge of 4% articaine hydrochloride with 0.002% epinephrine was administered via infiltration anesthesia (0.6–1.0 mL in the buccal mucosa and 0.2–0.3 mL in the palatal mucosa) in a patient with smokeless tobacco addiction. The anesthetic solution used in this study was manufactured by Exir Pharmaceutical Company, Iran.
Category
Treatment - Surgery

2

Description
:::writingOne cartridge containing 20 mg of lidocaine hydrochloride and 12.5 µg of epinephrine (as bitartrate) was administered via infiltration anesthesia (0.6–1.0 mL in the buccal mucosa and 0.2–0.3 mL in the palatal mucosa) in a patient with smokeless tobacco addiction. The anesthetic solution used in this study was manufactured by Loghman Pharmaceutical Company, Iran.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi University of Dentistry
Full name of responsible person
Iman Tavakoli
Street address
Yazd Province, Yazd, Dah-e-Fajr, W97M+8RF
City
YAZD
Province
Yazd
Postal code
8914881167
Phone
+98 35 3620 4760
Email
i.tavakolihosseini@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
دکتر مهران کریمی
Street address
Imam Reza Educational Complex Daneshjoo Blvd., Imam Hossein Sq. Yazd, Yazd Province Iran
City
YAZD
Province
Yazd
Postal code
8916188637
Phone
+98 35 3628 8114
Email

i.tavakolihosseini@ssu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Iman Tavakolihosaini

Position

Assistant Professor of Oral and Maxillofacial Surgery

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Yazd Province, Yazd, Dah-e-Fajr, W97M+8RF

City

Yazd

Province

Yazd

Postal code

8914881167

Phone

+98 35 3620 4760

Email

i.tavakolihosseini@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Iman Tavakolihosaini

Position

Assistant Professor of Oral and Maxillofacial Surgery

Latest degree

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Yazd

Province

Yazd

Postal code

8914881167

Phone

+98 35 3620 4760

Email

i.tavakolihosseini@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Iman Tavakolihosaini

Position

Assistant Professor of Oral and Maxillofacial Surgery

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City

Yazd

Province

Yazd

Postal code

8914881167

Phone

+98 35 3620 4760

Fax

Email

i.tavakolihosseini@ssu.ac.ir

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

“All data can potentially be shared after individuals are de-identified.”

When the data will become available and for how long

“All data can potentially be shared after individuals are de-identified.”

To whom data/document is available

"Our data will be available only to researchers affiliated with academic and scientific institutions."

Under which criteria data/document could be used

"If you require access to the results, please send a message to i.tavakolihosseini@ssu.ac.ir or Kiank1381@yahoo.com Or AlirezaRajol7720@gmail.com. Descriptive data will be reported as mean (with standard deviation), and demographic data will be presented as percentages. Statistical analyses will be performed using SPSS software (version 25). The Student's t-test will be used to compare whether the difference in pain levels between the two groups at the first 5 and 10 minutes is statistically significant. In addition, the significance of differences in pain changes (between the two pain assessment time points) between the intervention and control groups will be evaluated using a paired t-test. The significance of differences in patients' vital signs in both groups, recorded 30 minutes after tooth extraction, will also be assessed using a paired t-test. Any use of the data from this study for research projects is permitted. Upon registration of a research proposal, it will be possible to submit a request for access to the results of the present study."

From where data/document is obtainable

If you require access to the results, please send a message to i.tavakolihosseini@ssu.ac.ir or Kiank1381@yahoo.com Or AlirezaRajol7720@gmail.com.

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

To write a sample request for access to research results, the following points should be considered: Format: A formal and professional letter or email. Content: A brief introduction of the requester, the purpose of the request, a clear description of the required data or documents, a commitment to ethical principles (such as confidentiality and proper citation), and a specific request regarding the expected timeframe for receiving the data. Structure: Title, salutation, main body, expression of thanks, and signature. Based on your preference for conciseness and the use of abbreviations, the following text has been prepared in a compact and clearly structured format. Sample Request for Access to Research Results Subject: Request for Access to Research Data and Documentation Recipient: [Name of the Corresponding Author or Relevant Institution] Text: Dear Sir/Madam, I am [Your Full Name], [your academic position, e.g., Postdoctoral Researcher at University X]. I am currently conducting research in the field of [general research topic], which is closely related to your valuable work entitled "[Title of Your Article]." Purpose of the request: To complete comparative analyses and validate my findings, I kindly request access to the raw data and supplementary materials published with your article. Request details: Required data: Main dataset file(s) (CSV/Excel format). Documentation: Analysis codes (R/Python scripts) and any questionnaires or data collection protocols. Use: Exclusively for research purposes and in full compliance with ethical principles. Commitments: Ensuring data confidentiality. Proper citation of your article in any future publications. No data sharing with third parties without written permission. Timeline request: I would appreciate it if you could inform me of the approximate time required to review the request and provide the files. Typically, I expect this process to take no more than 10–14 working days. Thank you for your time and cooperation. Sincerely, [Your Full Name] [Email] [Institutional Affiliation]

Comments