Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Local Anesthetic Infiltration with Articaine 4% in Comparison to Inferior Alveolar Nerve Block with Lidocaine 2% for Mandibular 1st Molar Extraction

Protocol summary

Study aim
To compare the efficacy of a local anaesthetic infiltration of 4% articaine versus a regional block technique using 2% lidocaine on patients who need to have their first lower molar removed.

Design
controlled, parallel-group clinical trial

Settings and conduct
Patients are blinded

Participants/Inclusion and exclusion criteria
Patients eligible for mandibular 1st. molar extraction with no systemic, chronic, metabolic, or infectious disease

Intervention groups
Patients who need their Mandibular first Molar to be removed under local anaesthesia. The first group will receive 1.8 ml of 4% articaine with 1:100,000 epinephrine as lingual and buccal infiltration injection.

Main outcome variables
After extracting a non-restorable Mandibular first Molar, pain will be measured para-operatively using a verbal rating scale.

General information

Reason for update

Acronym
LATE

IRCT registration information
IRCT registration number: **IRCT20241220064111N1**
Registration date: **2025-01-11, 1403/10/22**
Registration timing: **retrospective**

Last update: **2025-01-11, 1403/10/22**
Update count: **0**

Registration date
2025-01-11, 1403/10/22

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-01, 1403/08/11

Expected recruitment end date
2024-11-30, 1403/09/10

Actual recruitment start date
2024-11-01, 1403/08/11

Actual recruitment end date
2024-11-30, 1403/09/10

Trial completion date
2024-12-01, 1403/09/11

Scientific title
Effectiveness of Local Anesthetic Infiltration with Articaine 4% in Comparison to Inferior Alveolar Nerve Block with Lidocaine 2% for Mandibular 1st Molar Extraction

Public title
Local Anesthesia for Tooth Extraction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subject with no systemic disease Subject

diagnosed for extraction of lower 1st. Molar

Exclusion criteria:

Patients with chronic Cardio-vascular disease Patients with infectious diseases Patients allergic to local anesthetic drug Pregnant ladies

Age

From **18 years** old to **63 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

When patients are diagnosed to be indicated for removal of non-restorable lower 1st. molar, they are allocated sequentially and arbitrarily to be included in either intervention groups one by one.

Blinding (investigator's opinion)

Single blinded

Blinding description

patients are not aware of the techniques used in the study

Placebo

Not used

Assignment

Parallel

Other design features

none

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee/Department of Oral and Maxillofacial surgery/College of Dentistry/Universi

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no.3, Al-Jamiea st.

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Approval date

2024-10-06, 1403/07/15

Ethics committee reference number

6876/2024

Health conditions studied

1

Description of health condition studied

Dental Caries, Tooth Fracture, destructive and non-restorable Mandibular 1st. Molar

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Local anesthetic technique

Timepoint

5 minutes

Method of measurement

patient description

Secondary outcomes

empty

Intervention groups

1

Description

The first group will receive a buccal and lingual infiltration injection of 1.8 ml of 4% articaine + 1:100,000 epinephrine local anesthetic pre-operatively using a dental syringe.

Category

Treatment - Drugs

2

Description

The second group will receive a conventional inferior alveolar nerve block technique (regional anesthesia) of 2% lidocaine + epinephrine (1:80,000) local anesthetic drug for tooth extraction, using an amount of 1.8 ml, pre-operatively using a dental syringe.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

College of Dentistry/University of Babylon

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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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
University of Babylon
Proportion provided by this source
20
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
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Person responsible for updating data

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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

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

DATA will be available on demand

When the data will become available and for how long

DATA will be available after publishing the study

To whom data/document is available

Everyone

Under which criteria data/document could be used

Dental Research

From where data/document is obtainable

From Authors

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

E-mail request

Comments