Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of anesthetic injection lidocaine with articaine on changes in heart rate ,blood oxygen saturation percentage and blood pressure in Candidate patients for tooth extraction: a Randomized clinical trial

Protocol summary

Study aim

General goal: to compare the effectiveness of injection of lidocaine anesthesia with articaine on heart rate, blood oxygen saturation percentage and blood pressure in patients who are candidates for tooth extraction.
functional goal: If the superiority of each is determined, it can be a good guide for dentists to choose an anesthetic agent.

Design

Clinical trial, double blind, phase 4 on 44 people, two parallel groups A block allocation table will be used for randomization

Settings and conduct

This study will be conducted on patients referred to Gorgan Dental Faculty. First, the patient rests upright for 5 minutes, and to evaluate the dental anxiety of the patients, the questionnaire of Stuttered et al. If the patient's dental anxiety is in the normal range (less than equal to 90), then the patient's heart rate (HR) and blood oxygen saturation (SPO2) were measured by a fingertip pulse oximeter before anesthesia injection. On the index finger of the patient's right hand, the blood pressure is also measured by a digital sphygmomanometer. Then the anesthetic injection is performed by the research associate student. And then the HR and SPO2 values are measured by the pulse oximeter on the same index finger. The blood pressure measurement will be done in the same way.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1) Healthy people between 30 and 50 years old 2) Candidates for extraction of lower jaw teeth Non-entry criteria: 1) People with cardiovascular, renal, respiratory disease, liver failure and hyperthyroidism 2) Pregnant women 3) All diabetic patients 4) People with dental anxiety outside the normal range 5) People who take drugs affecting heart rate

Intervention groups

In this study, we have 2 groups, one of which is injected with anesthetic lidocaine and the other with articaine.

Main outcome variables

heart beat Blood oxygen saturation blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240703062318N1**
Registration date: **2024-08-22, 1403/06/01**
Registration timing: **prospective**

Last update: **2024-08-22, 1403/06/01**
Update count: **0**

Registration date

2024-08-22, 1403/06/01

Registrant information

Name

Seyed Alireza Fazeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3224 1889

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alirezafazeli15@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anesthetic injection lidocaine with articaine on changes in heart rate ,blood oxygen saturation percentage and blood pressure in Candidate patients for tooth extraction: a Randomized clinical trial

Public title

Investigating the effectiveness of injection of lidocaine and articaine anesthesia on heart rate, blood oxygen saturation percentage and blood pressure

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy people between 30 and 50 years old Candidates for extraction of lower jaw teeth

Exclusion criteria:

People with cardiovascular, renal, respiratory disease, liver failure and hyperthyroidism pregnant women All diabetic patients People with dental anxiety outside the normal range People who take medications that affect heart rate

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Block allocation method: People are randomly assigned to articaine (A) and lidocaine (B) groups. Random block method will be used to assign people to groups. For this purpose, all six positions of letters A and B are considered in blocks of four as in the table below. AABB (1) ABAB (3) ABBA (5) BBAA (2) BABA(4) BAAB(6). 11 blocks of 4 are needed to allocate 22 samples in each group (44 people in total). To select 11 blocks first,11 random numbers between 1 and 6 will be generated by repetition (with placement). In this way, a sequence of letters A and B including 44 letters (22 letters A and 22 letters B) will be created.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind clinical trial study, all injections will be performed by a trained student (researcher) under the supervision of a maxillofacial surgeon (clinician), and the student will be aware of what kind of anesthetic to use for each patient will inject the anesthetic in opaque syringes to the patients and the patient will not know the type of anesthetic injected. Also, the person (nurse) who will measure the desired values (HR, SPO2 and BP) before and after the injection will not know what kind of anesthetic the patient has received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Hirkan boulevard , Central Organization of Golestan University of Medical Sciences and Healthcare Services

City

Gorgan

Province

Golestan

Postal code

4918936316

Approval date

2024-08-13, 1403/05/23

Ethics committee reference number

IR.GOUMS.REC.1403.181

Health conditions studied

1

Description of health condition studied

Blood pressure

ICD-10 code

ICD-10 code description

2

Description of health condition studied

heartbeat

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Blood oxygen saturation percentage

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Number of heartbeats
Timepoint
Before and after injection of anesthesia
Method of measurement
by pulse-oximetry

2

Description
Blood oxygen saturation
Timepoint
Before and after injection of anesthesia
Method of measurement
by pulse-oximetry

3

Description
Blood pressure
Timepoint
Before and after injection of anesthesia
Method of measurement
Digital pressure gauge device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving persocaine-E which contains lidocaine 2% with epinephrine 1/80000 from Darupakhsh company. Each patient will be injected only once and a carpool containing 1.8 ml of the anesthetic substance in one minute by inferior alveolar nerve block method.
Category
Treatment - Other

2

Description
Intervention group: Patients receiving Dentacaine 200 which contains articaine 4% with epinephrine 1/200000 from Exir pharmaceutical company. Each patient will be injected only once and one carpool containing 1.8 ml of anesthetic substance in one minute by inferior alveolar nerve block method. .
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Golestan University of Medical Sciences
Full name of responsible person
Seyed Alireza Fazeli
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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?
Yes
Title of funding source
Gorgan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
Seyed Alireza Fazeli

Position
student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Assistant Professor

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
After de-identifying individuals, the following information is shared: age gender Blood pressure before and after the injection of each anesthetic drug Blood oxygen saturation percentage before and after injection of each anesthetic drug The heart rate before and after the injection of each of the anesthetic drugs

When the data will become available and for how long
The access period starts 6 months after the results are published.

To whom data/document is available
Only for researchers working in academic and scientific institutions and students of medical sciences, including medicine, dentistry, pharmacy, etc.

Under which criteria data/document could be used
As a study resource for clinical science research

From where data/document is obtainable
By email to the responsible author of the article resulting from the study Mr. Seyed Alireza Fazeli Alirezafazeli15@gmail.com

What processes are involved for a request to access data/document
If the request is from colleagues and people working in the clinical fields of medical sciences, there will be no process.

Comments