

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of hemodynamic responses to epinephrine vasoconstrictor during infra alveolar nerve block and Gow-Gates mandibular anesthesia: A clinical trial

Protocol summary

Study aim

compare the hemodynamic responses to the vasoconstrictor epinephrine in two techniques of local anesthesia injection: the Gow-Gates (GG) technique and the inferior alveolar nerve block (IANB)

Design

A clinical trial with a control group, with parallel groups, double blinded, randomized, phase 2 on 20 patients.

Settings and conduct

20 candidates for bilateral extraction of mandibular third molar teeth participated. Before surgery, their characteristics including age and gender and their vital signs including heart rate (HR), oxygen saturation level, systolic blood pressure (SBP) and diastolic blood pressure (DBP) and ECG using a hospital monitoring device 5 minutes before the injection. was registered Randomly, lidocaine 2% and epinephrine 1:100,000 were extracted for the first tooth under GG injection and the second tooth under IANB injection. The mentioned hemodynamic variables were measured immediately, 2, 5, 10, 15 and 20 minutes after injection of anesthetic. Finally, after completing all the measurements, the patient's wisdom tooth removal surgery was performed.

Participants/Inclusion and exclusion criteria

Entry criteria: Candidates for bilateral surgery of asymptomatic mandibular impacted third molar teeth
Agreement to participate in the study
Exit criteria:
History of systemic disease
History of odontogenic pains in the last 7 days

Intervention groups

Intervention group one: Gow-Gates injection technique
Intervention group two: IANB injection technique (control)

Main outcome variables

The hemodynamic changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241004063259N1**

Registration date: **2024-12-08, 1403/09/18**

Registration timing: **retrospective**

Last update: **2024-12-08, 1403/09/18**

Update count: **0**

Registration date

2024-12-08, 1403/09/18

Registrant information

Name

Fardin Khodadadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5453 5298

Email address

fardinkh.work@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-11, 1403/07/20

Expected recruitment end date

2024-11-20, 1403/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic responses to epinephrine vasoconstrictor during infra alveolar nerve block and Gow-Gates mandibular anesthesia: A clinical trial

Public title

Comparison of hemodynamic responses to epinephrine vasoconstrictor during infra alveolar nerve block and Gow-Gates mandibular anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidates for bilateral surgery of asymptomatic mandibular impacted third molar teeth Agreement to participate in the study

Exclusion criteria:

History of systemic disease History of odontogenic pains in the last 7 days

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

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

In the present clinical trial, in order to investigate the effect of interventions, in each patient, by the split-mouth method, the impacted third molar teeth of the mandible on each side were randomly injected with lidocaine along with epinephrine with two techniques, IANB and GG.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization using a sealed envelope and patient selection. In this way, firstly, 2 envelopes, each containing one of the following (right, left) are provided to each patient and the patient selects only one of them. Then, 2 other envelopes, each containing one of the following (IANB and Gow-Gates), are provided to the patient and the patient selects one of them again. According to the study design, the side and type of the first technique are randomized and once the technique and side used are specified, the technique on the other side is also specified.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients were not aware of the technique used to inject anesthesia for each tooth (but they were aware of the general techniques used by IANB and Gow-Gates) and the researcher was not involved in measuring the investigated variables. Also, statistical analyzer was blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of North Khorasan University of Medical Sciences

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No. 7.2 , Qaem Maqam Ave, Farhang Blvd

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Province

Razavi Khorasan

Postal code

9188934339

Approval date

2024-10-05, 1403/07/14

Ethics committee reference number

IR.NKUMS.REC.1403.046

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

Hemodynamic responses

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Changes in hemodynamic variables

Timepoint

5 minutes before, 2, 5, 10, 15 and 20 minutes after injection

Method of measurement

Using a hospital monitoring device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: injection of local anesthesia with the

Gow-Gates method
Category
Treatment - Surgery

2

Description
Intervention group: injection of local anesthesia with the Infra Alveolar Nerve Block method

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
North Khorasan Faculty of Dentistry
Full name of responsible person
Fardin Khodadadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Vahide Motamed Sanaye
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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
Bojnourd 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
Bojnourd University of Medical Sciences
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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

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

Title and more details about the data/document

All conditions and results of this study will be available to everyone in the form of an article.

When the data will become available and for how long

Access starts 3 months after results are published

To whom data/document is available

The data of this study will be available to everyone.

Under which criteria data/document could be used

It will be possible to use the results of this study for clinical use as well as to use it in future studies by mentioning the source.

From where data/document is obtainable

It will be announced in the future.

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

It will be announced in the future.

Comments