Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Street address
No. 7.2 , Qaem Maqam Ave, Farhang Blvd
City
Mashhad
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

Full name of responsible person

Fardin Khodadadi

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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Position

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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