

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparision of Pain During Inferior Alveolar Nerve Block in Conventional and Two Stage Technique (New Modification)

Protocol summary

Study aim

Comparison of pain during inferior alveolar nerve block in conventional and two stage techniques (new modification).

Design

Clinical trial with two groups of 16 control (conventional technique) and intervention (double injection technique) in the age range of 20 to 60 years. With parallel, randomized, phase 2 groups on 32 patients. Excel software rand function was used for randomization. In this study, due to the nature of the intervention, it is not possible to blind the patient and the researcher.

Settings and conduct

Ask patient to sits on the dental unit and wait for 10 minutes till patient's heart rate be normalized. The vital sign device is connected to the patient to measure heart rate, blood pressure and respiratory rate, and the patient will be monitored. The injection is then performed in a conventional, two-stage manner in two groups (each group includes 16 people). The patient's vital signs are then monitored during the injection. Finally, the patient is asked to describe their pain using the NRS scale. The study is in the clinic of Sari Dental School.

Participants/Inclusion and exclusion criteria

Admission requirements: all people have a healthy systemic condition. Conditions of not entering: all people with systemic diseases and the use of drugs that change the perception of pain.

Intervention groups

For the two-injection method, the ICT device is used at the highest speed. The patient's vital signs are then monitored during the injection. In the control group, the injection is performed in a conventional manner and at the end the patient is asked to describe his pain using the NRS scale.

Main outcome variables

Pain rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220106053646N1**

Registration date: **2022-02-17, 1400/11/28**

Registration timing: **prospective**

Last update: **2022-02-17, 1400/11/28**

Update count: **0**

Registration date

2022-02-17, 1400/11/28

Registrant information

Name

Amirhossein Moaddabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3340 5474

Email address

s_bnf_s@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-05-21, 1401/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Pain During Inferior Alveolar Nerve Block in Conventional and Two Stage Technique (New Modification)

Public title

Comparison of Pain During Inferior Alveolar Nerve Block in Conventional and Two Stage Technique

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All people have healthy systemic conditions.

Exclusion criteria:

All people with heart and respiratory problems and high blood pressure People taking medications that change their perception of pain, such as corticosteroids.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

For random assignment of samples to two groups of 16, the blocking method will be used. For this purpose, six quadruple blocks will be considered. Six blocks are TCTC , TTCC, CTTC, CTCT, CCTT ,TCCT which T is for the intervention group and C is for the control group. The numbers will be generated randomly (with the RANDBETWEEN command in Excel software and in the range of 1 to 6). Depending on the production values, one of the blocks (for production number between 0 to 1 CTTC block, for production number between 1 to 2 CTCT blocks and so on) will be selected and samples will be assigned.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Central Headquarters of Mazandaran University of Medical Science , at the beginning of Valiasr Highway , Joybar Three Ways, Imam Square

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2022-02-08, 1400/11/19

Ethics committee reference number

IR.MAZUMS..REC.1400.12681

Health conditions studied**1****Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Pain rate

Timepoint

At the end of the injection, the patient is asked to describe his or her pain using the NRS scale

Method of measurement

Using the NRS scale

Secondary outcomes

empty

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

Intervention group: Benzocaine surface anesthesia gel is applied using an applicator in the needle entry area. Anesthesia drug containing vasoconstrictor will be used for anesthesia injection. ICT Injection device is used in two-stage injection. Needle heads used in two sizes of 12 and 25 mm with 30 gauge of transcendent brand will be used for inferior alveolar nerve block. In the first injection, we inject one third of the carpol with a 12 mm needle and after two minutes, we change the needle to 25 mm and inject two thirds of the carpol.

Category

Other

2**Description**

Control group: Benzocaine surface anesthesia gel is applied using an applicator in the needle entry area.

Anesthesia drug containing vasoconstrictor will be used for anesthesia injection . For the inferior alveolar nerve block in conventional injection, a 32 mm long needle with a 27 gauge from the Soha brand will be used.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sari Dental School Clinic

Full name of responsible person

Amir Hossein Moaddabi

Street address

Sari Dental School , next to Touba Medical Complex,
Khazar Boulevard,Sari

City

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4816895476

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+98 11 3324 4894

Email

m.moaddabi@mazums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Majid saeidi

Street address

Sari, Moallem Square, Vice Chancellor for Research,
Mazandaran University of Medical Sciences

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Mazandaran

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4817844718

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+98 11 3448 4800

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majsaeedi@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Amirhossein moaddabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Amirhossein moaddabi

Position

Assistant professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participants' files are private and cannot be shared.

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

Undecided - It is not yet known if there will be 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

Patient data includes age and sex and does not include private information.

When the data will become available and for how long

Start of access period 1 year after printing the results

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Documents and data can only be used for reference. The data will be provided to the applicant in case of urgent need.

From where data/document is obtainable

To receive data, postal correspondence to Sari Dental School of Mazandaran Province at the address: next to Toobi Medical Complex of Dental School, Farahabad Boulevard,Khazar Square, Sari . Postal code: 4816895476 Dr. Amir Hossein Modabi

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

After receiving the postal letter, the reply letter will be corresponded to the listed address within a maximum of two weeks.

Comments