Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the effect of needle entry angle on the amount of pain during premaxilla labial infiltration injection in patients referred to the special oral and maxillofacial surgery

Protocol summary

Study aim
Determining the effect of the needle entry angle on the amount of pain during the labial infiltration injection of the anterior of the maxilla in patients referred to the special oral and maxillofacial surgery clinic of the dental school of Sari city.

Design
Clinical trial with 4 intervention groups, with parallel groups, single-blind, randomized, on 36 patients. Randomization using Excel software

Settings and conduct
Immediately after the injection, the patient's pain level based on the NRS index and the patients' vital signs (blood pressure, heart rate and respiratory rate) will be recorded by the vital signs device, Mazandaran Dental Faculty Special Clinic

Participants/Inclusion and exclusion criteria
Healthy people 20 to 60 years old (ASA 1 & ASA 2) in terms of written records and oral questions, using the GHQ-28 general health questionnaire to equalize the volunteers psychologically, not using drugs that affect the perception of pain , with healthy systemic conditions and no active infection in the injection area and volunteers to participate in the research. People taking drugs that affect pain perception, having an active infection in the injection area, and having cardiovascular, respiratory, and blood pressure diseases will be excluded from the study.

Intervention groups
The volunteers are divided into four groups A-D (injection of labial infiltration in the anterior of the maxilla parallel to the longitudinal axis of the tooth with a normal syringe, injection of labial infiltration in the anterior of the maxilla with a new method and angle(α) with a normal syringe, injection of labial infiltration in the anterior of the maxilla using CCLAD parallel to the longitudinal axis of the tooth, injection of labial infiltration in the anterior of the maxilla using CCLAD with a new method and angle (α))

Main outcome variables
Pain level

General information

Reason for update
Fixing the mistake of accidentally removing two groups from the four study groups and making the randomization method more complete when registering information on the site

Acronym

IRCT registration information
IRCT registration number: **IRCT20230719058849N1**
Registration date: **2023-07-31, 1402/05/09**
Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**
Update count: **1**

Registration date
2023-07-31, 1402/05/09

Registrant information

Name
Dr.Alireza Arezoumandi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of needle entry angle on the amount of pain during premaxilla labial infiltration injection in patients referred to the special oral and maxillofacial surgery

Public title

Investigating the effect of needle entry angle on the amount of pain during premaxilla labial infiltration injection in patients referred to the special oral and maxillofacial surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy individuals (ASA 1 & ASA 2 based on American society of anesthesiologist classification) who are healthy in terms of written records (based on the individual's records in their medical record) and oral question (interview). The GHQ-28 general health questionnaire (available in the appendix) is used to equalize the participants psychologically. The validity and reliability of the questionnaire in Persian version is confirmed. Participants should not take any medication that alters their perception of pain. All participants have healthy systemic conditions and no active infection in the injection area. Individuals are volunteers to participate in the study. Candidates must be 20 to 60 years old.

Exclusion criteria:

Individuals who take drugs that change their perception of pain. Individuals who have an active infection in the injection area. Patients with cardiovascular, respiratory and blood pressure (over 15) diseases.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

All eligible people are randomly assigned to four groups (A-D) in the first stage. In the following, using Excel software, the samples are placed in 9 blocks of 4. (The total sample size is 36). Blocks of 4 are formed as ADCB, ADBC, ACDB, ACBD, ABDC, ABCD, etc.) For example: four people refer to the center where the groups are supposed to be assigned. In the Excel software, between the number 1 and 24, supposedly the number 2 is chosen by chance; Therefore, these four people are assigned to the ABDC block in the order of reference. In fact, the first person enters group A, the second person enters group B, the third person enters group D, and the fourth person enters group C.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, due to the nature of the intervention, it is not possible to blind the patient and the researcher, and only blinding will be done for data analysis.

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

Mazandaran University of Medical Sciences headquarters, the beginning of Valiasr highway, Imam Square, Sari

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.MAZUMS.REC.1401.520

Health conditions studied

1

Description of health condition studied

This study is not done on specific patients. Only the amount of pain after different injection techniques will be investigated and compared.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The amount of pain after injection
Timepoint
Immediately after injection
Method of measurement
Using a numerical rating scale (NRS 0-10), the pain level is evaluated. This scale has points from 0 to 10 and the patient is asked to specify the level of pain in the index [61].

Secondary outcomes

1

Description
Blood pressure
Timepoint
Before, during and after injection
Method of measurement
When the patient sits on the dental chair, we wait 10 minutes until the patient's heart rate, blood pressure, and respiratory rate return to normal. Then the vital sign device (CMS 6000 brand made in China) is connected to the patient to measure heart rate, blood pressure and respiratory rate and the patient is monitored. For adults, normal blood pressure is defined as 120/80 (mmHg). After the patient is connected to the vital sign measuring device, blood pressure is recorded before the injection. Then once during the injection and finally immediately after the injection blood pressure is recorded and compared with the initial level.

2

Description
Heart beat
Timepoint
Before, during and after injection
Method of measurement
When the patient sits on the dental chair, we wait 10 minutes until the patient's heart rate, blood pressure, and respiratory rate return to normal. Then the vital sign device (CMS 6000 brand made in China) is connected to the patient to measure heart rate, blood pressure and respiratory rate and the patient is monitored. For adults, a normal heart rate is defined as 80 to 100 beats per minute (bpm). After the patient is connected to the vital sign measuring device, the heart rate is recorded before the injection. Then, once during the injection and finally immediately after the injection, the heart rate is recorded and compared with the initial rate.

3

Description
Respiratory rate
Timepoint
Before, during and after injection
Method of measurement
When the patient sits on the dental chair, we wait 10 minutes until the patient's heart rate, blood pressure, and respiratory rate return to normal. Then the vital sign device (CMS 6000 brand made in China) is connected to the patient to measure heart rate, blood pressure and respiratory rate and the patient is monitored. For adults, normal breathing is defined as 12 to 20 breaths per minute. After the patient is connected to the vital signs measurement device, first before the injection, the respiratory rate is recorded. Then once during the injection and finally immediately after the injection, the respiratory rate is recorded and compared with the initial rate.

Intervention groups

1

Description
Intervention group: Group A: injection of labial infiltration in the anterior of the maxilla parallel to the longitudinal axis of the tooth with a normal syringe - in this group anesthesia, in the form of infiltration, in the apex of the maxillary left central tooth by conventional method or parallel to the longitudinal axis of the tooth using a normal syringe and a 12 mm short needle head of 30 gauge and lidocaine anesthetic agent with epinephrine 1:100000 in the amount of 1.2 ml (approximately equivalent to two thirds of the cartridge) are applied to the patient in the semi-supine position.
Category
Treatment - Devices

2

Description
Intervention group: Group B: labial infiltration injection in the anterior of the maxilla with a new method and angle (α) with a normal syringe - in this group anesthesia, in the form of infiltration, in the apex area of the left central tooth of the maxilla with a new method so that in this method first three anatomical planes (sagittal-occlusal-frontal) are considered. Then, the needle is inserted at an angle α (65 degrees to the sagittal plane or the longitudinal axis of the tooth/35 degrees to the occlusal plane/80 degrees to the frontal plane) in the depth of the mucobuccal fold of the maxillary left central tooth. The injection is applied to the patient in the semi-supine position using a regular syringe and a short needle head of 30 gauge and an anesthetic agent of lidocaine with epinephrine 1:100000 in the amount of two thirds of the cartridge.
Category
Treatment - Devices

3

Description
Intervention group: Group C: labial infiltration injection in the anterior of the maxilla using CCLAD parallel to the longitudinal axis of the tooth - in this group anesthesia, in the form of infiltration, in the apex of the maxillary left central tooth by conventional method or parallel to the longitudinal axis of the tooth using the computerized

injection technique and 12 mm short needle head 30 gauge and lidocaine anesthetic agent with epinephrine 1:100000 in the amount of 1.2 ml (approximately equivalent to two thirds of the cartridge) is applied to the patient in the semi-supine position.

Category

Treatment - Devices

4

Description

Intervention group: Group D: Labial infiltration injection in the anterior of the maxilla using CCLAD with a new method and angle (α) - in this group anesthesia, in the form of infiltration, in the apex area of the left central tooth of the maxilla in a new way so that in this method First, three anatomical planes (sagittal-occlusal-frontal) are considered. Then, the needle is inserted at an angle α (65 degrees to the sagittal plane or the longitudinal axis of the tooth/35 degrees to the occlusal plane/80 degrees to the frontal plane) in the depth of the mucobuccal fold of the maxillary left central tooth. The injection is applied to the patient using a computerized injection technique and a 30-gauge short needle head and an anesthetic agent of lidocaine with epinephrine 1:100,000 in the amount of two-thirds of the cartridge in the semi-supine position.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghban Special Dental Clinic

Full name of responsible person

Amirhossein Moaddabi

Street address

Baghban Dental Clinic, Khazar Boulevard, Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Street address

Mazandaran University of Medical Sciences and Health Services Building No. 2, Moalem Square, Sari, 3rd floor, Research and Technology Vice-Chancellor

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Web page address

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

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

Mazandaran University of Medical Sciences

Full name of responsible person

Amirhossein Moaddabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Oral and maxillofacial surgery

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Person responsible for scientific

inquiries

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Full name of responsible person
Amirhossein Moaddabi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Dentistry student

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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
After the completion of the study and the publication of the resulting article,all the mentioned documents will be available upon request from the researcher author.

When the data will become available and for how long
The start of the access period, 6 months after the publication of the article resulting from the project.

To whom data/document is available
All people

Under which criteria data/document could be used
All documents will be available upon request from the responsible researcher.

From where data/document is obtainable
Responsible researcher: Dr. Amirhossein Moaddabi, address: Khazar Blvd., Mazandaran, Sari, Baghban Dental Clinic, contact number: 09127103916 and email: a.moaddabi2@gmail.com

What processes are involved for a request to access data/document
It can be received from the responsible researcher through a personal visit, phone call or e-mail.

Comments