

# 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( $\alpha$ ) 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 ( $\alpha$ ))

##### 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)

###### Phone

+98 51 3846 9144

###### Email address

alirezaarezoomandi.7619@gmail.com

##### 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 ( $\alpha$ ) 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  $\alpha$  (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 ( $\alpha$ ) - 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  $\alpha$  (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

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816895475

**Phone**

+98 11 3324 4894

**Email**

a.moaddabi2@gmail.com

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr.Pedram Ebrahimnejad

**Street address**

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

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3325 7230

**Email**

pajhooheshi@mazums.ac.ir

**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

**Street address**

Baghban Dental Clinic, Khazar Boulevard, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816895475

**Phone**

+98 11 3324 4894

**Email**

a.moaddabi2@gmail.com

**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Amirhossein Moaddabi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Oral and maxillofacial surgery

**Street address**

Baghban Dental Clinic, Khazar Boulevard, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4819895475

**Phone**

+98 11 3324 4894

**Email**

a.moaddabi2@gmail.com

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Alireza Arezoumandi

**Position**

Dentistry student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

Baghban Dental Clinic, Khazar Boulevard, Sari

**City**

ساری

**Province**

Mazandaran

**Postal code**

4816895479

**Phone**

+98 11 3324 4894

**Email**

alirezaarezoomandi.7619@gmail.com

## **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**