

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of the effect of needle temperature on the intensity of pain due to inferior alveolar nerve block injection of children 5-10 years old.

#### Protocol summary

2013-05-19, 1392/02/29

##### Summary

Generally local anesthetic injection is one of the dental procedure that makes the most negative respond in the children and reduce the pain of this is one of the big challenge in the children dentistry. 40 volunteer children that need bilaterall inferior alveolar injection with similar treatment indication in 2 side of mandible will participate in this study. The inferior alveolar block injection will be performed by cold needle and needle with room temperature in 2 side of mandible. In half of children randomly in first session will used needle with room temperature and for the other half vice versa. For preparation of cold needle, needles will put in the freezer in -7°C . the selection of the side of injection ( right or left) and kind of first injection ( with cold needle or needle with room temperature ) will be randomly. Injection will performed by specialist in pediatric dentistry that will be same for all and the constant assistant ( student) who will help the injector in dental procedures and evaluate the intensity of the pain injection by sound, eyes and movement of children. . before the injection will be used the benzocain gel for 30 second. the interval between the session will be 1 week. Criteria for Pain Scale: sound scale, eyes, movements (SEM) are part of the behavioural -assessments of pain scale.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013050413218N1**  
Registration date: **2013-05-19, 1392/02/29**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Elham Hosseini

###### Name of organization / entity

Zahedan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 937 203 9978

###### Email address

drelhamhosseini@zaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Research and Technology Assistance of Zahedan University of Medical Science

##### Expected recruitment start date

2013-04-06, 1392/01/17

##### Expected recruitment end date

2013-05-28, 1392/03/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of needle temperature on the intensity of pain due to inferior alveolar nerve block injection of children 5-10 years old.

##### Public title

evaluation of cold needle on anesthetic injection pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: children 5-10 years old who needs

bilateral inferior alveolar injection with similar treatment indication in 2 side of mandible and those who will be in cooperative group (frankle 3-4). Exclusion criteria: children with systemic disease, mental retardation, history of dental treatment, Sensitivity to anesthetics, Taking medicines that affect pain and any abscess and fistula in the desired area.

#### **Age**

From **5 years** old to **10 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **40**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Zahedan University of Medical Science

##### **Street address**

Zahedan University of Medical Science, Dr. Hesabi square

##### **City**

Zahedan

##### **Postal code**

9817699693

#### **Approval date**

2013-04-13, 1392/01/24

#### **Ethics committee reference number**

61-92

## **Health conditions studied**

### 1

#### **Description of health condition studied**

injection pain

#### **ICD-10 code**

R52.0

#### **ICD-10 code description**

Acute pain

## **Primary outcomes**

### 1

#### **Description**

injection pain

#### **Timepoint**

during injection

#### **Method of measurement**

sum of the points of voice, eye and movement according to SEM parameters. point 3(minimum pain intensity) to 12(maximum pain intensity).

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

needle with room temperature

#### **Category**

Other

### 2

#### **Description**

cold needle

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Pediatric Department, Zahedan Dental School

##### **Full name of responsible person**

Mitra Zare

##### **Street address**

Dental School, east Azadegan street.

##### **City**

Zahedan

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Research and Technology Assistance of Zahedan University of Medical Science

##### **Full name of responsible person**

Dr. Hamid Reza Mahmoodzade Sagheb

##### **Street address**

Zahedan University of Medical Science, Dr. Hesabi square

**City**  
Zahedan

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

**Title of funding source**  
Research and Technology Assistance of Zahedan University of Medical Science

**Proportion provided by this source**  
100

**Public or private sector**  
*empty*

**Domestic or foreign origin**  
*empty*

**Category of foreign source of funding**  
*empty*

**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Zahedan University of Medical Science

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Mitra Zare

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Dental Student

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## Person responsible for scientific inquiries

### Contact

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Specialist in Pediatric Dentistry

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## Person responsible for updating data

### Contact

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*

**Study Protocol**  
*empty*

**Statistical Analysis Plan**  
*empty*

**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*