Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Summary

Generally local anesthethic 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 dentidtry. 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

2013-05-19, 1392/02/29

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
Full name of responsible person
Mitra Zare
Position
Dental Student
Other areas of specialty/work
Street address
Bozorgmehr 36
City
Zahedan
Postal code
Phone
+98 54 1241 0411
Fax
Email
zare.m19@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Science
Full name of responsible person
Elham Hosseini
Position
Specialist in Pediatric Dentistry
Other areas of specialty/work
Street address
Dental school, east Azadegan street
City
Zahedan
Postal code
Phone
+98 54 1244 1824
Fax
Email
drelhamhosseini@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Science
Full name of responsible person
Mitra Zare
Position
Dental student
Other areas of specialty/work
Street address
Bozorgmehr 36
City
Zahedan
Postal code
Phone
+98 54 1241 0411
Fax
Email
zare.m19@gmail.com
Web page address

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