

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of analgesia and anxiety amount due to mandibular nerve block via QuickSleeper in primary mandibular molar teeth pulp therapy of children aged 6 to 8 years

Protocol summary

Study aim

Evaluation of analgesia and anxiety amount due to mandibular nerve block via QuickSleeper in pulp therapy of primary mandibular molar teeth of children aged 6 to 8 years

Design

Twenty eligible children aged 6 to 8 with the need of vital pulp therapy on the both sides of the mandible (40 teeth) that referred to pediatric department of Shahid Sadoughi Dental school of yazd are selected.

Settings and conduct

This study is a randomized clinical trial study. At the first session the injection has done randomly by one of the anesthetic method (block or intraosseous technique) and after 7 to 21 days, the same tooth at the opposite side of the mandible done by another method. Patients' pain and anxiety during injection and treatment is measured by Visual Analog Scale and Venham picture test, Venham anxiety score, pulse oximeter respectively.

Participants/Inclusion and exclusion criteria

Children aged 6 to 8 with the need of vital pulp therapy on the primary molars in both sides of the mandible.

Intervention groups

At the first session the injection has done randomly by one of the anesthetic method (block or intrabone technique) and after 7 to 21 days, the same tooth at the opposite side of the mandible done by another method.

Main outcome variables

Analgesia and anxiety amount due to mandibular nerve block via QuickSleeper

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171013036745N1**

Registration date: **2018-01-04, 1396/10/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-04, 1396/10/14**

Update count: **0**

Registration date

2018-01-04, 1396/10/14

Registrant information

Name

fatemeh kebriiae

Name of organization / entity

Dental Faculty, ShahidSadoughiuniversity of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 35362558814

Email address

f.kebriaee@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of analgesia and anxiety amount due to

mandibular nerve block via QuickSleeper in primary mandibular molar teeth pulp therapy of children aged 6 to 8 years	
Public title	The effect of intra-bone injection in reducing pain and anxiety
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	(Children without systemic disease (disability, autism, cancer, heart disease, sickle cell anemia, etc.) ; Children whose score according to modified Venham behaviore scale is less than 3 ; Patients who have not used analgesics within 48 hours before treatment ; Children needing vital pulp therapy on similar primary molars in both sides of the mandible (with clinical and radiological confirmation) ; Parental and patient consent ; Parental and patient consent)
Exclusion criteria:	(Children who do not attend the second treatment session ; Children with necrosis teeth)
Age	From 6 years old to 8 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 20 More than 1 sample in each individual Number of samples in each individual: 2 Vital pulp therapy on similar primary molars in both sides of the mandible
Randomization (investigator's opinion)	Randomized
Randomization description	simple individual randomization by table of random numbers
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Single
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee in Shahid Sadoughi University of Medical Sciences Yazd
Street address	Shahid Bahonar Square, Central Organization of Shahid Sadoughi University of Medical Sciences, Yazd
City	Yazd
Province	Yazd
Postal code	8916978477
Approval date	2017-06-20, 1396/03/30
Ethics committee reference number	IR.SSU.REC.1396.73
Health conditions studied	
<u>1</u>	
Description of health condition studied	anxiety
ICD-10 code	F41.9
ICD-10 code description	Anxiety NOS
<u>2</u>	
Description of health condition studied	Dental pain
ICD-10 code	k08.8
ICD-10 code description	Toothache NOS
Primary outcomes	
<u>1</u>	
Description	Pain
Timepoint	During injection, During treatment
Method of measurement	Visual analogue scale
<u>2</u>	
Description	Anxiety
Timepoint	During injection, During treatment
Method of measurement	Venham picture test, Venham anxiety score, Pulse oximeter
Secondary outcomes	empty

Intervention groups

1

Description

Injection with quicksleeper device (a type of intra bony injection) would be used in the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Faculty, ShahidSadoughi University of Medical Sciences

Full name of responsible person

Mahboube Daneshvar

Street address

Faculty of Dentistry, DaheyeFajr Blvd, Imam Ave

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8914881167

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Daneshvar.m68@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mrs Khezri

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Faculty of Dentistry Shahid Sadoughi University

Full name of responsible person

Mahboube Daneshvar

Position

Pediatric dentistry resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Kebriaee

Position

Assistant Professor Department of Pediatric Dentistry

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

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Full name of responsible person
Mahboube Daneshvar
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Medical doctor
Other areas of specialty/work
Pediatrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All collected deidentified individual Participant Data

When the data will become available and for how long

Starting 2 months after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

There is no limitation for what types of analyses will be used.

From where data/document is obtainable

Mahboube Daneshvar/ daneshvar.m68@gmail.com/
09378670497

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

The applicant sends a request by sending an e-mail to the above-mentioned email; after reviewing his/her request, the data file will be sent to him/her within a maximum of one month

Comments