Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 randeomly by one of the anesthesic 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 kebriaee

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

1

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

1

Description of health condition studied
anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety NOS

2

Description of health condition studied
Dental pain
ICD-10 code
k08.8
ICD-10 code description
Toothache NOS

Primary outcomes

1

Description
Pain
Timepoint
During injection, During treatment
Method of measurement
Visual analogue scale

2

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
City
Yazd
Province
Yazd
Postal code
8914881167
Phone
+98 35 3625 5881
Email
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
Street address
Faculty of Dentistry, DaheyeFajr Blvd, Imam Ave, Yazd ,
City
Yazd
Province
Yazd
Postal code
8914881167
Phone
+98 35 3625 5881
Email
pajoheshdentyazd@gmail.com
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
Street address
Faculty of Dentistry, DaheyeFajr Blvd, Imam Ave, Yazd,
City
Yazd
Province
Yazd
Postal code
8914881167
Phone
+98 35 3625 5881
Fax
Email
daneshvar.m68@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Kebriaiee
Position
Assistant Professor Department of Pediatric Dentistry
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Faculty of Dentistry, DaheyeFajr Blvd, Imam Ave, Yazd,
City
Yazd
Province
Yazd

Postal code
8914881167
Phone
+98 35 3625 5881
Fax
Email
f.kebriaee@ssu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mahboube Daneshvar
Position
Pediatric dentistry resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Faculty of Dentistry, DaheyeFajr Blvd, Imam Ave, Yazd,
City
Yazd
Province
Yazd
Postal code
8914881167
Phone
+98 35 3625 5881
Email
Daneshvar.m68@gmail.com

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