

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation Of Analgesia And Anxiety Amount Due To inferior alveolar block injection Via Intraosseous injection with QuickSleeper In hypomineralized Mandibular Molar Teeth during apexogenesis in children 7 to 10 years old

Protocol summary

Study aim

Evaluation of analgesia and anxiety amount due to inferior alveolar block injection Via Intraosseous injection with QuickSleeper In hypomineralized Mandibular Molar Teeth during apexogenesis in children 7 to 10 years old

Design

Twenty eligible children aged 7 to 10 with the need of apexogenesis on hypomineralized Molar Teeth in 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.

Participants/Inclusion and exclusion criteria

Children aged 7 to 10 with the need of apexogenesis on hypomineralized Molar Teeth in the both sides of the mandible

Intervention groups

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

Main outcome variables

Analgesia and anxiety amount due to inferior alveolar block via QuickSleeper

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171013036745N2**

Registration date: **2018-01-24, 1396/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-24, 1396/11/04**

Update count: **0**

Registration date

2018-01-24, 1396/11/04

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

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-04-20, 1397/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Of Analgesia And Anxiety Amount Due To inferior alveolar block injection Via Intraosseous injection with QuickSleeper In hypomineralized Mandibular Molar Teeth during apexogenesis in children 7 to 10 years old

Public title

The effect of Intraosseous injection in reducing pain and anxiety in children with hypomineralized Mandibular Molar

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 behavior scale is less than 2 Patients who have not used analgesics within 48 hours before treatment Children needing apexogenesis on hypomineralized Molars Teeth in both sides of the mandible (with clinical and radiological confirmation) Parental and patient consent Teeth without periodontal disease and radiographic lesions

Exclusion criteria:

Children who do not attend the second treatment session Children with necrosis teeth

Age

From **7 years** old to **10 years** old

Gender

Both

Phase

3

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**

apexogenesis In hypomineralized Mandibular Molar

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

Crossover

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

2017-11-04, 1396/08/13

Ethics committee reference number

IR.SSU.REC.1396.132

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

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

before injection, During injection, During treatment

Method of measurement

Children's Fear Survey Schedule-Dental Subscale and Venham anxiety score

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Treatment - Other

2

Description

Control group: inferior alveolar block Injection would be used in the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Faculty, ShahidSadoughi University of Medical Science

Full name of responsible person

Fatemeh Zarebidoki

Street address

Faculty of Dentistry, DaheyeFajr Blvd, Imam Ave

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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

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Zarebidoki

Position

Pediatric dentistry resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Kebriaiee

Position

Assistant Professor Department of Pediatric Dentistry

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Specialist
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Person responsible for updating data

Contact
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Yazd University of Medical Sciences
Full name of responsible person
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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
Fatemeh Zarebidoki / fzarebidoki@yahoo.com
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