

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of two needle tip designs, Sebtoject and NOP, on pain perception during inferior alveolar nerve block injections in 6 to 8 years old children

Protocol summary

Study aim

1. Determination and comparison the participants' characteristics (age, gender, rating of infant birth) in group AB & BA. 2. Determination and comparison the pain average based on face scale when injecting septoject and NOP in 6 to 8 infants. 3. Determination and comparison the pain average based on SME scale, when injecting block inferior nerve, between septoject and NOP in 6 to 8 infants. 4. Determinate the correlation between SME and face scale in 6 to 8 infants.

Design

The population of this study in the first period, randomly were divided in 2 equal groups and for this purpose we used of permuted block randomization method. The permuted block randomization was downloaded from <http://randomization.com> freely. 1. AB____ 2. AB____ 3. BA____ 4. BA____ 5. BA____ 6. AB____ 7. AB____ 8. BA____ 9. BA____ 10. AB____ 11. BA____ ... 30

Settings and conduct

This study is performed as a cross-sectional clinical trial in children aged 6 to 8 years referred to one of the pediatric dental treatment centers in Bushehr in 2020-2021.

Participants/Inclusion and exclusion criteria

Informing parents and gaining informed consent to participate in the study Children are 6 to 8 years old The patient has two stages of treatment (visit twice)

Intervention groups

Common septoject needle intervention (intervention A)
NOP needle intervention (intervention B)

Main outcome variables

The amount of pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210720051947N1**

Registration date: **2021-08-22, 1400/05/31**

Registration timing: **retrospective**

Last update: **2021-08-22, 1400/05/31**

Update count: **0**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Sima Jokar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3332 3226

Email address

s.jokar@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two needle tip designs, Sebtoject and NOP, on pain perception during inferior alveolar nerve

block injections in 6 to 8 years old children

Public title
Comparison of two needle tip designs ,Sebtoject and NOP on pain perception during injections

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Informing parents and gaining informed consent to participate in the study Children are 6 to 8 years old The patient has two stages of treatment (visit twice)
Exclusion criteria:
Withdrawal from the study History of allergy to anesthetic solution or contraindication to anesthesia History of systemic diseases or special conditions that endanger public health Taking painkillers in the last two months

Age
From **6 years** old to **8 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
This study is two period cross over clinical trail. Based on this study the patients were presented in 2 frequency, 2 periods and 2 symbols, BA & AB. In AB group, the first period (A intervention) received septoject intervention and the second one (B intervention) received NOP intervention. But in BA group right inverse the former, we observe in the first period NOP intervention and in the second one septoject intervention for injecting the analgesia medicine. The population of this study in the first period, randomly were divided in 2 equal groups and for this purpose we used of permuted block randomization method. The permuted block randomization was downloaded from <http://randomization.com> freely.

Blinding (investigator's opinion)
Double blinded

Blinding description
The population of the study randomly was divided in 2 equal group, A & B. Group A in the first visit received septoject needle and in the second one, NOP needle for injecting the analgesia medicine. Group B right inverse, patients in the first visit received NOP needle and in the second section, septoject for injecting the analgesia medicine (cross design A&B). It is better to mention that just the dentist knows the order of permuted block randomization and participants' arrival; so evaluator should not observe the kind of intervention and the scale of block. We can say that attribution of data will be

hidden until the end of study.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Bushehr University of Medical Sciences
Street address
Rishehr, Bandar Bushehr, Bushehr province
City
Bushehr
Province
Boushehr
Postal code
7514633341
Approval date
2021-03-07, 1399/12/17
Ethics committee reference number
IR.BPUMS.REC.1399.195

Health conditions studied

1

Description of health condition studied
Inferior alveolar nerve block injections

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain intensity score

Timepoint
Measurements immediately after the first and second injections

Method of measurement
1: Face criterion 2: Objective evaluation with SEM scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the group of patients that receive NOP. This needle is made in South Korea and because of silicone cover beside trihedral needle's top, cause less bleeding and trauma or even eliminate it during injection.

Category

Treatment - Devices

2**Description**

Control group: the group receive sebtobject needle.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Personal office of Dr. Sima Jokar

Full name of responsible person

Dr. Sima Jokar

Street address

Emam Khomeini

City

Bushehr

Province

Bushehr

Postal code

7515735336

Phone

+98 77 3462 2515

Email

s.jokar@bpums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bushehr University of Medical Sciences

Full name of responsible person

Gholamreza Khamisipour

Street address

Bushehr University Of Medical Sciences

City

Bushehr

Province

Bushehr

Postal code

7518759577

Phone

+98 77 1455 2247

Fax

+98 77 1455 2247

Email

Ghr.Khamisi@Gmail.Com

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

Yes

Title of funding source

Bushehr 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**

Bushehr University of Medical Sciences

Full name of responsible person

Sima Jokar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Bushehr University of Medical Sciences., Bushehr .,
bushehr province

City

Bushehr

Province

Bushehr

Postal code

7518759577

Phone

+98 77 3332 3226

Fax**Email**

s.jokar@bpums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bushehr University of Medical Sciences

Full name of responsible person

Sima Jokar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Bushehr University of Medical Sciences., Bushehr .,

bushehr province
City
Bushehr
Province
Boushehr
Postal code
7518759577
Phone
+98 77 3332 3226
Fax
Email
s.jokar@bpums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Sima Jokar
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Bushehr University of Medical Sciences., Bushehr .,
bushehr province
City
Bushehr
Province

Boushehr
Postal code
7518759577
Phone
+98 77 3332 3226
Fax
Email
s.jokar@bpums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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