

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of pain and stress during dental treatment of children using palatal anesthesia in trans papillary and computerized anesthesia methods

Protocol summary

Study aim

Comparison of pain and stress during dental treatment of children using palatal anesthesia in trans papillary and computerized anesthesia methods

Design

This study is a clinical trial. In this study, 18 patients with children aged 5-8 years who are referred to the private office of Dr. Hamid Sarlak, a pediatric dentist in Arak, will be studied. This study is a clinical trial double-blind.

Settings and conduct

This study is a clinical trial. In this study, 18 patients with children aged 5-8 years who are referred to the private office of Dr. Hamid Sarlak, a pediatric dentist in Arak, will be studied. This study is a clinical trial double-blind. Outcome assessor and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for bilateral pulpotomy and SCC treatment in high molar molar teeth, lack of any unpleasant dental history, lack of systemic disease, absence of genetic disease. Exclusion criteria: Lack of cooperation

Intervention groups

In the first group, in the first session of the palatal injection of the trans-papillary (control) method, and in the second session, the injection was performed using a computer device (ICT injection GENOSS, Gyeonggi-do, South Korea) (test). In the second group, in the first session of treatment, palatal injection was performed using the ICT injection computer (test) and in the second session, using a trans-papillary (control) method.

Main outcome variables

Pain, stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N101**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-06, 1398/01/17**

Update count: **0**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of pain and stress during dental treatment of children using palatal anesthesia in trans papillary and computerized anesthesia methods

Public title
Comparison of pain and stress during dental treatment of children using palatal anesthesia in trans papillary and computerized anesthesia methods

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for bilateral pulpotomy and SCC treatment in high molar teeth
Lack of any unpleasant dental history
Lack of Systemic Disease
Absence of genetic disease
Exclusion criteria:
Lack of cooperation

Age
From **5 years** old to **8 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **18**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with random number in division of groups in two groups A and B. Randomized patients are divided into two groups. The candidate patients who enter the study are randomly assigned to the randomly assigned table of randomly assigned to the two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Outcome assessor and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Ethics Committee Arak University Of Medical Sciences

Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2018-12-19, 1397/09/28

Ethics committee reference number
IR.ARAKMU.REC.1397.287

1

Description of health condition studied
Bilateral pulpotomy

ICD-10 code
K02

ICD-10 code description
Dental caries

<u>1</u>	
Description	pain
Timepoint	While injecting anesthetics and during pulp exposure
Method of measurement	Faces Pain Rating Scale

Description	pain
Timepoint	While injecting anesthetics
Method of measurement	Sound Eye Motor Pain

Description	stress
Timepoint	While injecting anesthetics and during pulp exposure
Method of measurement	objective

empty

Intervention groups

1

Description

Intervention group: In the first group, in the first session of the palatal injection of the trans-papillary (control) method, and in the second session, the injection was performed using a computer device (ICTinjection GENOSS, Gyeonggi-do, South Korea) (test).

Category

Treatment - Devices

2

Description

Intervention group: In the second group, in the first session of treatment, palatal injection was performed using the ICTinjection computer (test) and in the second session, using a trans-papillary (control) method.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental clinic

Full name of responsible person

Dr Hamid Sarlak

Street address

Payambar Azam Complex, Basij square, Sardasht, Arak

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Arak

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3848176941

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+98 86 3417 3645

Email

sarlak@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University Of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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Email

arjmandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Shima Nourmohamadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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Payambar Azam Complex, Basij square, Sardasht, Arak

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Hamid Sarlak

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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dr.ehsanimanesh@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Sarlak

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

They have to write letters to the professors and the university

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Navid Ehsani manesh

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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City

Arak

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