

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of needle gauge on pain during injection of infiltration in buccal maxillary incisor teeth: A crossover randomized clinical trial

Protocol summary

Study aim

To assess the effect of needle gauge on pain during injection of infiltration in buccal maxillary incisor teeth

Design

This is a crossover randomized clinical trial, in which 38 eligible patients will be randomly assigned to the intervention 1 and 2 groups.

Settings and conduct

The eligible children needing to the treatment of buccal maxillary incisor teeth referring to the School of Dentistry in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention 1 and 2 groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 5 to 7 years, Need to treat two similar incisor teeth on both sides of the maxilla, Having positive behavior based on the Frankel scale
Exclusion criteria: Abscesses, cellulite or oral infections

Intervention groups

Intervention group 1: Injection of infiltration in buccal maxillary incisor teeth with needle number 30 for the first time and then after 14 days injection of infiltration in buccal maxillary incisor teeth with needle number 27
Intervention group 2: Injection of infiltration in buccal maxillary incisor teeth with needle number 27 for the first time and then after 14 days injection of infiltration in buccal maxillary incisor teeth with needle number 30

Main outcome variables

Primary outcome: Pain in the injection site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N365**

Registration date: **2020-08-24, 1399/06/03**

Registration timing: **prospective**

Last update: **2020-08-24, 1399/06/03**

Update count: **0**

Registration date

2020-08-24, 1399/06/03

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-06, 1399/06/16

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of needle gauge on pain during injection of infiltration in buccal maxillary incisor teeth: A crossover randomized clinical trial

Public title

Effect of needle gauge on pain during injection of infiltration in buccal maxillary incisor teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 5 to 7 years, Need to treat two similar incisor teeth on both sides of the maxilla, Having positive behavior based on the Frankel scale

Exclusion criteria:
Abscesses, cellulite or oral infections

Age
From **5 years** old to **7 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the right and left sides of the patients to the intervention 1 and 2 groups through the drawing of lots. To do this, we prepare two sheets and write "right" on one sheet and "left" on another. Then, by referring to every patient, one of the sheets will be randomly taken. According to whether the sheet is taken right or left is assigned to the interventions-1 group and the other side to the interventions-2 group.

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 of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-07-26, 1399/05/05

Ethics committee reference number

IR.UMSHA.REC.1399.410

Health conditions studied

1

Description of health condition studied

Tooth Decay

ICD-10 code

K03.81

ICD-10 code description

Cracked tooth

Primary outcomes

1

Description

Pain in the injection site

Timepoint

On the first and 14th days

Method of measurement

Using Wong-Baker FACES scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Injection of infiltration in buccal maxillary incisor teeth with needle number 30 for the first time and then after 14 days injection of infiltration in buccal maxillary incisor teeth with needle number 27

Category

Treatment - Devices

2

Description

Intervention group 2: Injection of infiltration in buccal maxillary incisor teeth with needle number 27 for the first time and then after 14 days injection of infiltration in buccal maxillary incisor teeth with needle number 30

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry in Hamadan city

Full name of responsible person

Atefeh Jamshidi

Street address

School of Dentistry, Hamadan University of Medical

Sciences, Shahid Fahmideh Ave.

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+98 81 3838 0572

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ati123jamshidi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Hamedan University of Medical Sciences

Full name of responsible person

Atefeh Jamshidi

Position

Student of Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Zahra Khosravi

Position

Pediatric Dentist

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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