

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of gel Benzocaine 18% versus gel Menthol 10% and 5% on local dentistry injection pain in children 3 to 6 years old: a double-blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of gel Benzocaine 18% versus gel Menthol 10% and 5% on local dentistry injection pain in children 3 to 6 years old. Design: a double blind randomized clinical trial. Setting and conduct: The eligible 3-6 years old children who will refer to Hamadan School of Dentistry during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 3 to 6 years; (b) the first dentistry local anesthesia injection; (c) require to repair the first or second molar of the maxilla. Exclusion criteria: (a) restless child; (b) history of previous dentistry injection; (c) contraindication for anesthesia; (d) absence of the first or second molar of the maxilla; (e) havinf systemic, psychological, or mental disorder, (f) presence of oral abscess or lesions. Intervention: (a) putting gel Menthol 10% on the location of injection for 30 seconds; (b) putting gel Menthol 5% on the location of injection for 30 seconds. Control: putting gel Benzocaine 18% on the location of injection for 30 seconds. Primary outcome: measuring the pain severity just after injection using VAS scale. Secondary outcome: nothing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501189014N53**
Registration date: **2015-01-21, 1393/11/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-21, 1393/11/01

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2012-12-30, 1391/10/10

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of gel Benzocaine 18% versus gel Menthol 10%
and 5% on local dentistry injection pain in children 3 to 6
years old: a double-blind randomized clinical trial

Public title

Effect of gel Benzocaine 18% versus gel Menthol 10%
and 5% on local dentistry injection pain in children 3 to 6
years old

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 3 to 6 years; (b) the first dentistry local anesthesia injection; (c) require to repair the first or second molar of the maxilla. Exclusion criteria: (a) restless child; (b) history of previous dentistry injection; (c) contraindication for anesthesia; (d) absence of the first or second molar of the maxilla; (e) havinf systemic, psychological, or mental disorder, (f) presence of oral abscess or lesions.

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: the patients will be randomly allocated to the intervention and control groups using random numbers table. Blinding: the gels stained with the anesthetic drugs will be put on the location of injection for 30 seconds by a physician. Then, the injection and measuring the pain will be done by another physician. Neither the patients not the second physician will be aware of the type of anesthetic drugs. Therefore, the trial will be run as double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

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

City

Hamadan

Postal code

6517838695

Approval date

2012-04-22, 1391/02/03

Ethics committee reference number

D/P/16/35/9/242

Health conditions studied

1

Description of health condition studied

Injection pain

ICD-10 code

R52

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

measuring the pain severity

Timepoint

just after injection

Method of measurement

using VAS scale

Secondary outcomes

1

Description

Nothing

Timepoint

Nothing

Method of measurement

Nothing

Intervention groups

1

Description

putting gel Menthol 10% on the location of injection for 30 seconds

Category

Treatment - Drugs

2

Description

putting gel Menthol 5% on the location of injection for 30 seconds

Category

Treatment - Drugs

3

Description

putting gel Benzocaine 18% on the location of injection for 30 seconds

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Roya pahlavani

Street address

School of Dentistry, Shahid Fahmideh Ave.

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Pharmacologist

Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan 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

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Pharmacy

Full name of responsible person

Dr Fatemeh Zeraati

Position

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Dentistry

Full name of responsible person

Roya Pahlavani

Position

Lecturer

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty