Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Metal and Cartoon Syringes on Dental Anxiety and Pain Perception of Healthy Children Aged 6-8 Years Attending to Babol University of Medical Sciences: A Clinical Trial

Protocol summary

Summary

Objective: This study aims to compare the effect of the cartoon and metal syringes on pain perception and dental anxiety of children. Design: Two twenty-set groups of cooperative healthy children aged 6-8 years. Setting and conduct: In the cross-over clinical trial, two twenty-set groups of cooperative healthy children aged 6-8 years were tested within two treatment sessions. At the beginning of the first and second appointments, the metal and cartoon syringes were respectively displayed to the first group in reveres to the second group of children and the dental anxiety was assessed by Children's Fear Survey Schedule-Dental Subscale (CFSS-DS),Venham Picture Test (VPT) and Facial Image Scale (FIS). Score of pain was also evaluated by Face Scale at the end of sessions. Statistical analysis of data was done using the T-test and paired T-test with the significance level at $p<0.05$. Participants: Six to eight year-old children with no systemic, mental or psychological diseases who had two decayed primary maxillary first molars which needed pulpotomy and were not previously under local anesthesia. Interventions: Displaying the mental or cartoon syringes to children within two dental appointments. Primary outcome: The score of dental anxiety

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040421519N2**
Registration date: **2015-06-08, 1394/03/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-08, 1394/03/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Metal and Cartoon Syringes on Dental Anxiety and Pain Perception of Healthy Children Aged 6-8 Years Attending to Babol University of Medical Sciences: A Clinical Trial

Public title

Dental Anxiety and Pain Concerning the Appearance of Dental Injector

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Children who had at least two decayed upper primary first molars which needed pulpotomy No history of local anesthesia. Exclusion criteria: History of systemic diseases, mental or psychological disorders and acute pain.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

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 Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganj Afrooz street, Babol

City

Babol

Postal code

Approval date

2011-01-24, 1389/11/04

Ethics committee reference number

30/2865/پ/ز

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

Primary outcomes

1

Description

Score of anxiety

Timepoint

Immediately following the intervention

Method of measurement

Children's Fear Survey Schedule-Dental Subscale (CFSS-DS), Venham Picture Test (VPT) and Facial Image Scale (FIS)

Secondary outcomes

1

Description

Pain

Timepoint

At the end of treatment

Method of measurement

Face scale

Intervention groups

1

Description

Intervention: Displaying the conventional stainless steel dental syringe to the children of group 1 and 2, at the beginning of the first and second treatment sessions respectively. In overall two times for a couple of minutes.

Category

Treatment - Devices

2

Description

Intervention: Displaying the cartoon covered stainless steel syringe to the children of group 2 and 1 at the beginning of the first and second treatment sessions respectively. In overall, two times for a couple of minutes.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol University of Medical Sciences

Full name of responsible person

Street address

City

Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Babol University of Medical Sciences
Full name of responsible person
Ali Akbar Moghadamnia
Street address
Babol University of Medical Sciences, Ganj Afrooz street, Babol
City
Babol
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, Babol 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
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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