

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Clinical trial comparative evaluation of pain perception during anesthetic injection by Smartject and conventional technique

Protocol summary

Summary

Injection of local anesthesia is one of the most frightening and anxiety inducing stimuli in dental practice. Many methods have been introduced to reduction of pain during injection of local anesthesia. Computed controlled automatic anesthesia delivery system(Smartject) is one of the methods that is introduced for treatment of pain. It is one of the several non pharmacological techniques that is used to reduction of pain. Due to the limited data available on the use of Smartject in dentistry so, we have designed a randomized clinical trail study to compare Smartejct and conventional injection technique for pain control during anesthetic injection in dental patients. The present study is a randomized clinical trial. The subjects consist of 50 volunteer dental students aged 23-28 years (boy and girl), studying in dental school of Shiraz University of Medical Sciences. Exclusion criteria: Subjects with history of systemic disease; Subjects with abscess, redness or fistula in injection site. The Split mouth design is applied in the current study. Base on black randomization table all of the participants will be assigned to receive anesthetic gel and Smartject (Korea) on one side of maxillary premolar buccal mucosa and anesthetic gel and conventional injection technique on other side of maxillary premolar buccal mucosa. The dentist will record pain perception due to injection in both groups based on VAS (Visual Analogue Scale) and SEM scale (Sounds, Eye signs and Body Movement) .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101024445N2**

Registration date: **2016-03-24, 1395/01/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-24, 1395/01/05

Registrant information

Name

Mahboobe Ahmadbeigi

Name of organization / entity

Shiraz University of Medical Sciences

Country

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Phone

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ahmadbeigim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2017-01-01, 1395/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparative evaluation of pain perception during anesthetic injection by Smartject and conventional technique

Public title

Comparative evaluation of pain perception during anesthetic injection by Computed controlled automatic anesthesia delivery system and conventional technique

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: Subjects with history of systemic disease; Subjects with abscess, redness or fistula in injection site

Age

From **23 years** old to **28 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The Split mouth design is applied in the current study. Base on Black randomization table all of the participants will be assigned to receive anesthetic gel and Smartject (Korea) on one side of maxillary premolar buccal mucosa and anesthetic gel and conventional injection technique on other side of maxillary premolar buccal mucosa.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Lule building, Karimkhanzand blvd, Shiraz, Fars, Iran

City

Shiraz

Postal code

71936-65395

Approval date

2015-11-07, 1394/08/16

Ethics committee reference number

ir.sums.rec.1394.123

Health conditions studied

1

Description of health condition studied

local anesthesia

ICD-10 code

XXI

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes

1

Description

Effect of Smartject on pain perception during injection

Timepoint

Immediately after intervention

Method of measurement

VAS (Visual Analogue Scale) and SEM scale (Sounds, Eye signs and Body Movement)

Secondary outcomes

empty

Intervention groups

1

Description

All of the participants will be assigned to receive anesthetic gel on one side of maxillary premolar buccal mucosa (intervention) then injection will be performed by Smartject (Korea). (intervention)

Category

Treatment - Drugs

2

Description

All of the participants will be assigned to receive anesthetic gel on other side of maxillary premolar buccal mucosa then conventional injection will be performed. (control)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University of Medical Sciences, School of Dentistry

Full name of responsible person

Mahboobe Ahmadbeigi

Street address

Department of Pediatric, School of Dentistry. Ghom abad, Ghasrodasht street, Shiraz, Fars, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Center of research

Street address

Lule building, Karimkhan zand blvd, Shiraz, Fars, Iran

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences, School of dentistry

Full name of responsible person

Mahboobe Ahmadbeigi

Position

Pediatric dentistry assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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Web page address

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