

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Clinical trial comparing the effects of standard dental needles and telescopic needles to reduce the pain and anxiety of patients who refer to the dental clinic in Kerman city

Protocol summary

Summary

1) Objectives: To compare the pain and anxiety associated with dental injection using standard needles and telescopic needles. 2) Design: New invented telescopic needles with the ability of using of local anesthetic gel and covering the needle appearance compare with standard dental needles in reducing pain and anxiety injection . 3) The 100 patients admitted to the dental clinic were randomly placed in two groups (intervention and control) and injected with standard needles or telescopic needles and the pain and anxiety of injection compared between the two groups. 4) Inclusion criteria Participants: Restoration of teeth D and E in children and teeth number 6,7 in adults under local anesthesia ; The ability to communicate with the audience; No specific systemic disease; Patients in the 48 hours prior to treatment have not used any analgesia . 5) Exclusion criteria: patients with underlying systemic problem ; Patients with the disability to communicate with the audience, patients with dental pain; Children in single-parent 6) Interventions: dental pain and anxiety have compared in patients who have used conventional needles and telescopic needles . 7) The main outcome variables: pain after injection checked using the Visual Analogue Scale and anxiety before and after injection examined using Venham Scale questionnaire to assess the effectiveness of the new telescopic dental needles

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015113025300N1**
Registration date: **2016-01-05, 1394/10/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-05, 1394/10/15

Registrant information

Name

Raha HabibAgahi

Name of organization / entity

Oral and dental research center

Country

Iran (Islamic Republic of)

Phone

+98 917 811 8417

Email address

raha2979@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the effects of standard dental needles and telescopic needles to reduce the pain and anxiety of patients who refer to the dental clinic in Kerman city

Public title

Telescopic coated dental needles vs. conventional syringe system: comparing pain and anxiety in patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: the need for similar dental treatment under local anesthesia (restoration of teeth number D and E in children and teeth number of 6,7 in adults); Ability to speak and communicate with the audience; The lack of any developmental delay; The lack of a specific systemic disease; patients do not have pain when entering the study ; Patients in the 48 hours before the dental work are not analgesics. Exclusion criteria: patients with speech problems and lack the ability to communicate with the audience; Patients with systemic problem; Single-parent's children ; Patients with a history of dental pain.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Tahmasbabad Square

City

Kerman

Postal code

Approval date

2015-11-23, 1394/09/02

Ethics committee reference number

IR.KMU.REC.1394.312

Health conditions studied

1

Description of health condition studied

Pain & Anxiety

ICD-10 code

F40, F41,

ICD-10 code description

Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description

Pain

Timepoint

After injection

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Anxiety

Timepoint

Before and after of injection

Method of measurement

Venham's anxiety scale

Secondary outcomes

1

Description

The interest of patients to refer for later dental procedures

Timepoint

After first dental injection and treatment

Method of measurement

Questionair

Intervention groups

1

Description

In the intervention group, patients were injected by new telescopic needle that covered the needle appearance during injection, and also by using lidocaine gel before needle insertion, it has the ability to reduce the pain and anxiety during injection .

Category

Behavior

2

Description

In the control group conventional and standard needles were used , and the pain and anxiety induced in this group examined with pain and anxiety questionnaire.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Arya dental clinic

Full name of responsible person

Mr. Ehsan Zamani

Street address

Jahad BLVD. 56-58

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of
Medical Sciences

Full name of responsible person

Ms. Hasani

Street address

Tahmasbabad Square

City

Kerman

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, Kerman 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

Dental and Oral Research Center

Full name of responsible person

Dr. Raha HabibAgahi

Position

Dentist, PhD of dental materials

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman Dental School

Full name of responsible person

Dr. Maryam Hashemipor

Position

Oral and Dental Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Dentist

Other areas of specialty/work

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kerman

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00

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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