

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of relation between pressure pain threshold and pain severity of anterior maxillary infiltration injection

Protocol summary

Study aim

Given that little research has been done on examining the relationship between a person's actual pain threshold and what it expresses by the severity of the pain, we found it useful to find the similarity or difference of pain expressed by anesthetic injection and pain threshold and to determine whether the pain reported from The patient is affected by factors such as anxiety, fear of needle and injection, and then compare it with the actual threshold of pain via compression pain threshold (other than the needle and injection process).

Design

Clinical trial, easy sampling, two groups with more and less pain threshold

Settings and conduct

At each visit, the threshold of compressive pain is measured using an algometer method (other than dental) and then the severity of pain due to infiltration of the maxillary infiltration (in the dental setting) is recorded by the VAS method. Of all subjects, 50% of those with higher pain thresholds (group B) compared with 50% of those with lower pain thresholds (group A) compared the severity of sensations associated with injections of maxillary infiltration, and the results were compared. The following is reported.

Participants/Inclusion and exclusion criteria

General health, lidocaine insensitivity, non-sedation and antidepressant medication for two weeks, no myofascial pain and cervical cramps, no dental pain during the past month

Intervention groups

Of those who met the criteria, 200 were selected by easy sampling. At first, pain thresholds are measured by algometric method and then divided into two groups with higher and lower pain thresholds. The two groups underwent topical anesthesia and the patient's reported pain was compared with the pain threshold.

Main outcome variables

Pain threshold, pain during injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190803044415N1**

Registration date: **2019-08-05, 1398/05/14**

Registration timing: **prospective**

Last update: **2019-08-05, 1398/05/14**

Update count: **0**

Registration date

2019-08-05, 1398/05/14

Registrant information

Name

amirhossein azimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8847 2511

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of relation between pressure pain threshold and pain severity of anterior maxillary infiltration injection

ir.kums.rec.1398.265

Public title

Evaluation of relation between pressure pain threshold and pain severity of anterior maxillary infiltration injection

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

general health Not allergic to lidocaine Lack of toothache over the past month

Exclusion criteria:

Use of sedatives and antidepressants over the past two weeks Myofascial pain and neck cramps

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kermanshah University of Medical Sciences

Street address

padis, Amiriyeh Towers, Block Iale 2, Floor 8, Unit 8

City

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Province

Kermanshah

Postal code

6718815785

Approval date

2019-06-24, 1398/04/03

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

The Relationship between Pressure Pain Threshold and Pain from Anesthesia Injection

ICD-10 code

F43.8

ICD-10 code description

Other reactions to severe stress

Primary outcomes

1

Description

pressure pain threshold

Timepoint

At the beginning of the intervention

Method of measurement

Taiwanese Lutron power meter with a measuring accuracy of 0.01 kg

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After recalling patients to the Restoration section, volunteers fill out a Beck Anxiety Inventory to determine the level of anxiety. Of those who met the criteria, 200 were selected by easy sampling. At each visit, the threshold of compressive pain is measured using an algebraic method (other than dental) and then the severity of pain due to infiltration of the maxilla (in the dental setting) is recorded by the VAS method. Of all subjects, 50% of those with higher pain thresholds (group B) compared with 50% of those with lower pain thresholds (group A) compared the severity of sensations associated with injections of maxillary infiltration, and the results were compared. The following is reported.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Dental School

Full name of responsible person

Amirhossein Azimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
70
Public or private sector
Public
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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr Roohallh Sharifi Lorestani
Position

Associate professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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Position
student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Registered forms are provided

When the data will become available and for how long

12 months after printing the results

To whom data/document is available

Kermanshah Dental School Professors

Under which criteria data/document could be used

Possibility of re-investigation

From where data/document is obtainable

Dr Rohallah Sharifi

What processes are involved for a request to access data/document

Initially, the request will be sent by email, then the documents will be presented in person.

Comments