Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of efficacy of pain vibrator in reduction of dental injection pain

Protocol summary

Study aim
Determining the effect of vibrator apparatus on pain relief during dental anesthesia injections
Design
A randomized controlled clinical trial with Control and parallel groups. The sample size is 36 and the study phase is 3.
Settings and conduct
Patients who refered to the dental clinics of Hamadan University of Medical Sciences and require standardized bilateral and identical dental injections for one treatment will be selected. In this study, blindness will not be performed.
Participants/Inclusion and exclusion criteria
Inclusion criterion: Requiring standard bilateral dental injections. Non-inclusion criterion: needing concurrent surgery
Intervention groups
In the intervention group, on one side a standard injection of one carpel volume without the use of a vibrator done and on the opposite side, the same injection is performed in the same way as a standard carpal volume, but without the use of a vibrator in the vicinity of the injection site. In the control group, standard injection is performed with one carpel volume without the use of the vibrator.
Main outcome variables
Pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170117032025N6**
Registration date: **2020-03-21, 1399/01/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-21, 1399/01/02**
Update count: **0**

Registration date
2020-03-21, 1399/01/02

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-02-20, 1398/12/01
Expected recruitment end date
2020-05-21, 1399/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of efficacy of pain vibrator in reduction of dental injection pain

Public title
Efficacy of vibrator device on dental injection's pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Requiring standard bilateral dental injections
Exclusion criteria:
History of vibrator use

Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were divided into six blocks of size 6 based on random block allocation. Three samples from each block were placed in the experimental group and three samples in the control group.
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
Hamadan University of Medical Sciences
Street address
Shahid Fahmideh boulvard
City
Hamadan
Province
Hamadan
Postal code
7615665175
Approval date
2019-10-26, 1398/08/04
Ethics committee reference number
IR.UMSHA.REC.1398.608

Health conditions studied

1

Description of health condition studied
Pain during the dental procedure
ICD-10 code
K08.3
ICD-10 code description
Retained dental root

Primary outcomes

1

Description
Pain
Timepoint
During dental procedure
Method of measurement
By The visual analogue scale (VAS) index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: On one side a standard injection of one carpel volume without the use of a vibrator done and on the opposite side, the same injection is performed in the same way as a standard carpal volume, but without the use of a vibrator in the vicinity of the injection site.
Category
Treatment - Surgery

2

Description
In the control group, standard injection is performed with one carpel volume without the use of the vibrator.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental clinics affiliated to Hamadan University of Medical Sciences
Full name of responsible person
Dr Ali Heidari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan University of Medical Sciences
Proportion provided by this source
100
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
Hamedan University of Medical Sciences
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Dr Ali Heidari
Position
Faculty Member
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available