

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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 referred 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 carpal 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 carpal 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

###### Name

Arash Khalili

###### Name of organization / entity

Hamadan University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 0320

###### Email address

a.khalili@umsha.ac.ir

##### 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 boulevard

**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

**Street address**

Shahid Fahmideh street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838698

**Phone**

+98 81 3525 0182

**Email**

aliheidari55@gmail.com

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Saeed Bashirian

**Street address**

Shahid Fahmideh street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838698

**Phone**

+98 81 3525 0182

**Email**

aliheidari55@gmail.com

**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

**Full name of responsible person**

Dr Ali Heidari

**Position**

Faculty Member

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Shahid Fahmideh street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838698

**Phone**

+98 81 3525 0182

**Email**

aliheidari55@gmail.com

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Ali Heidari

**Position**

Faculty Member

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Shahid Fahmideh street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838698

**Phone**

+98 81 3525 0182

**Email**

aliheidari55@gmail.com

### Person responsible for updating data

**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Arash Khalili

**Position**

Faculty Member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Fahmideh street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838698

**Phone**

+98 81 3525 0182

**Email**

arash5920@yahoo.com

### 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