

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The impact of acidic foodstuff on dentine hypersensitivity in treatment with anti hypersensitivity toothpaste among patients of Kerman school of dentistry

#### Protocol summary

##### Summary

Aim: In this clinical trial, the aim of the study includes as evaluating the effect of using soft tooth brush besides eliminating acidic foodstuff from the diet of the patients who suffered from dentine hypersensitivity. Methods: This study will be conducted in Kerman School of Dentistry. A total number of 36 patients who are systemically well fit and have at least two teeth with dentin hypersensitivity will be selected. Moreover, at the first examination session, their response to cold air stimulator should be categorized at least 2 -3 and 3-8 in Schiff and Visual Analogue Scales for pain respectively. Then, after 10 minutes, the VAS and Schiff scales will be recorded again using ice spray at the buccal surface of the tooth. In addition, the Gingival Index will be measured too. Consequently, each patient will receive a package containing as follows: Package A: 1.Anti hypersensitive toothpaste, 2. soft tooth brush 3.instructional pamphlet. Package B: 1.Anti hypersensitive toothpaste, 2. soft tooth brush 3.instructional pamphlet 4.instructions related to patients diet. It should be noted that all the packages will be coded by another operator while the dentist and patient will be blinded. Then the patient will be asked to use only the packages content for tooth brushing and follow the instructions completely. Finally, at the four weeks follow up session, the VAS, Schiff will be recorded again to compare with the baseline data in order to evaluate the effect of treatment protocol.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017070534903N1**

Registration date: **2017-09-18, 1396/06/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-09-18, 1396/06/27

##### Registrant information

###### Name

Faeze Hamze

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3247 6498

###### Email address

f\_hamzeh@kmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Kerman University of Medical Sciences

##### Expected recruitment start date

2017-08-06, 1396/05/15

##### Expected recruitment end date

2017-11-06, 1396/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The impact of acidic foodstuff on dentine hypersensitivity in treatment with anti hypersensitivity toothpaste among patients of Kerman school of dentistry

##### Public title

Effect of non-acidic diet in treating dentin

hypersensitivity: A randomized clinical trial double blind

## **Purpose**

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: patients age must be within the range of 18-70; in the first session of examinations, patients must have at least two teeth with dentin hypersensitivity in which erosion or abrasion in cervical region or gingival recession is exposed; initially, in response to cold air stimulator, patients must choose 2 or 3 in Schiff scale and choose within the range of 30 to 80 milli metres (3 to 8) in visual analogue scale pain intensity specifier, then after 10 minutes, using ice spray and putting it in buccal surface, we ask the patients to specify the intensity of pain based on visual analogue scale; mentioned teeth must not have looseness degree greater than one; Gingival Index must be equal or lower than one in the teeth under consideration; patients access and control must be available within the four week period of treatment. Exclusion criteria: people with systemic diseases (people with high blood pressure or diabetic ones who are under control are excepted ); ladies who are in the period of pregnancy or breast feeding; people who have used anti epilepsy, anti inflammation, anti histamine, anti depression, anodyne, tranquilizer or sedative drugs daily, in the recent month or have to use during the period of study; people with chronic or advanced periodontal or dental pathologic diseases; teeth with partial prosthesis, teeth with wide restoration such as crowned teeth, suspected to pulpitis, enamel caries or cracking; people who have used dentin hypersensitivity reduction treatment like anti hypersensitivity toothpaste in the recent eight weeks; patients who have had periodontal surgery orthodontic treatment in the recent three months.

## **Age**

From **18 years** old to **70 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **36**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Kerman University of Medical Sciences

##### **Street address**

Ebne Sina street, Jahad boulevard, Somaye (Tahmasb Abad) corssroads

##### **City**

Kerman

##### **Postal code**

##### **Approval date**

2017-07-10, 1396/04/19

##### **Ethics committee reference number**

IR.KMU.REC.1396.1054

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Dentin hypersensitivity

#### **ICD-10 code**

K03.8

#### **ICD-10 code description**

Other specified diseases of hard tissues of teeth

## **Primary outcomes**

### 1

#### **Description**

pain amount in the first examination and before intervention

#### **Timepoint**

At the beginning of the study in the primary examination

#### **Method of measurement**

visual analog scale Marking on the line with standard length

### 2

#### **Description**

pain amount in the first examination and before intervention

#### **Timepoint**

At the beginning of the study in the primary examination

#### **Method of measurement**

Schiff criteria Degree 0: patient does not answer to the air stimulator , degree 1: patient answers to the air stimulator but does not ask for its stop, degree 2: patient answers to the air stimulator and ask for its stop or dispalcement, degree 3: patient answers to the air stimulator, finds it painful and ask for its stop.

## **Secondary outcomes**

## 1

### Description

Visual analogue scale degree in the final examination and before intervention

### Timepoint

4 weeks

### Method of measurement

Marking on the line with standard length (pain amount identifier)

## 2

### Description

Schiff criteria degree in the final examination and after intervention

### Timepoint

4 weeks

### Method of measurement

Degree 0: patient does not answer to the air stimulator , degree 1: patient answers to the air stimulator but does not ask for its stop, degree 2: patient answers to the air stimulator and ask for its stop or displacement, degree 3: patient answers to the air stimulator, finds it painful and ask for its stop.

## Intervention groups

### 1

#### Description

Intervention group, treatment packages, contain soft Oral-B tooth brush and Sensodyne toothpaste And contained a brochure on diet and food.After the initial examinations, the patient was asked Which uses toothbrushes and toothpastes inside the package for 4 weeks, Using foodstuff and drinks with high acidity level is not allowed during 4 weeks. Therefore, forbidden foodstuffs in this this period are as followed : 1. acid drinks ( beverage , beer, fizzy and not fizzy yogurt drinks ) 2. greek yogurt or very sour yogurt 3. whey and qarequrut 4. pickles and salty stuff (anything that contains vinegar, such as pickled cucumber, salad sauce ...) 5. citrus ( drinking citrus juice by using straw, the way that straw is placed at the end of the mouth and the juice does not contact the teeth, does not make any problem in the process of treatment) 6. lemon juice and verjuice

#### Category

Lifestyle

### 2

#### Description

Control group, treatment packages, contain soft Oral-B tooth brush and Sensodyne toothpaste.After the initial examinations, the patient was asked Which uses toothbrushes and toothpastes inside the package for 4 weeks.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Dentistry

##### Full name of responsible person

Fatemeh Akhavan Fard

##### Street address

##### City

Kerman

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Endodontology Research Center, Kerman University of Medical Sciences

##### Full name of responsible person

Dr Abbas Pardakhti

##### Street address

next to Kowsar salon, kowsar boulevard, Kowsar square

##### City

Kerman

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Endodontology Research Center, 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

School of Dentistry

##### Full name of responsible person

Fatemeh Akhavan Fard

##### Position

Student

##### Other areas of specialty/work

##### Street address

Shafa street

##### City

Kerman

**Postal code**  
**Phone**  
+98 34 3246 6839  
**Fax**  
**Email**  
fatemeh.akhavanfard@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
School of Dentistry  
**Full name of responsible person**  
Faeze Hamze  
**Position**  
assistant Professor  
**Other areas of specialty/work**  
**Street address**  
Shafa street  
**City**  
Kerman  
**Postal code**  
**Phone**  
+98 34 3247 6498  
**Fax**  
**Email**  
faeze.hamze@gmail.com  
**Web page address**

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Akhavan Fard  
**Position**  
Student  
**Other areas of specialty/work**  
**Street address**  
**City**  
**Postal code**  
**Phone**  
00  
**Fax**  
**Email**  
fatemeh.akhavanfard@gmail.com  
**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*