Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Name of organization / entity
Kerman University of Medical Sciences
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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 bind

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 metes (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 periodental or dental pathologic diseases; teeth with partial prosthesis, teeth with wide restoration such as crowned teeth, suspected to pulpit, 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 periodental 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 hypersensivity

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 dispalcement, 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
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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