

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### **A comparative efficacy of 50% ethanol extract of propolis , composition of 50% ethanol extract of propolis and nanohydroxyapatite and placebo in dentinal hypersensitivity treatment : a double blind study**

#### **Protocol summary**

##### **Summary**

This study is a randomized, double-blind controlled clinical trial (patient and pain assessor were blinded, the other was known materials and did the intervention). Inclusion criteria were patients who attended in Dental School of Shahid sadoughi University of Medical Sciences, Yazd, Iran, sensitive teeth with signs of abrasion, erosion or cervical dentin's exposure. Exclusion criteria were teeth with evidence of pulpitis, caries lesions, defective restorations, enamel's crack, active periodontal disease, decay or deterioration in the cervical area that needs to class V fillings, cracked or endodontically treated teeth; teeth with large restoration; fixed prosthesis or as abutment of removable prosthesis; daily intake of anti-inflammatory drugs, analgesics, tooth desensitizer; patients with surgical periodontal or orthodontic treatment in the last 3 months; suppressed immune systems; pregnant and lactating patients; systemic conditions is caused or predictive factor for DH or too much acidic diet. After selecting appropriate patients, informed consent was filled by patients and they were enrolled. Cluster randomization was done with unequal clusters (the number of sensitive teeth per person). From by random numbers table, patients divided into three groups. Depending on the number sensitive teeth per person sample size had been completed in each groups. The adjacent teeth were isolated with cotton rolls and then air blast was vertically applied by 2cm in 3 seconds. Tactile stimulation was done by swiping and vertically explorer's pressure on cervical area of tooth which was gradually increased. The sensitivity of the patients was measured by a VAS scale. After baseline assessment, 3 desensitizing agents including propolis (A), HA (B) and placebo (C) were applied and up to 5 minutes remained isolated. It is also recommended not washing their mouth for next 30 minutes. In the beginning of study, the same soft

toothbrush and toothpaste were given to them to use twice a day (morning and evening before bedtime). Pain score were measured 2 and 4 weeks after the intervention.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT2016011911888N2**

Registration date: **2016-05-03, 1395/02/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### **Registration date**

2016-05-03, 1395/02/14

##### **Registrant information**

###### **Name**

Motahare Amiri

###### **Name of organization / entity**

Yazd Dental Faculty

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 35 1625 5881

###### **Email address**

motahare.amiri@ssu.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

shahid sadoughi university , Yazd, Iran

##### **Expected recruitment start date**

2015-08-23, 1394/06/01

##### **Expected recruitment end date**

2016-01-21, 1394/11/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparative efficacy of 50% ethanol extract of propolis , composition of 50% ethanol extract of propolis and nanohydroxyapatite and placebo in dentinal hypersensitivity treatment : adouble blind study

**Public title**

The effect of propolis and nanohydroxyapatite in treatment of dentin hypersensitivity.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria were patients who attended in Dental School of Shahid sadoughi University of Medical Sciences, Yazd, Iran, sensitive teeth with signs of abrasion, erosion or cervical dentin's exposure. Exclusion criteria were teeth with evidence of pulpitis, caries lesions, defective restorations, enamel's crack, active periodontal disease, decay or deterioration in the cervical area that needs to class V fillings, cracked or endodontically treated teeth; teeth with large restoration; fixed prosthesis or as abutment of removable prosthesis; daily intake of anti-inflammatory drugs, analgesics, tooth desensitizer; patients with surgical periodontal or orthodontic treatment in the last 3 months; suppressed immune systems; pregnant and lactating patients; systemic conditions is caused or predictive factor for DH or too much acidic diet.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 55

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Yazd Shahid Sadoughi University of Medical Sciences

**Street address**

central organization of shahid sadoughi medicine university ,Shahid Bahonar square, yazd , Iran

**City**

Yazd

**Postal code**

8916978477

**Approval date**

2015-07-26, 1394/05/04

**Ethics committee reference number**

IR.SSU.REC.1394.66

**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

**Timepoint**

Before intervention, 2 and 4 weeks after intervention

**Method of measurement**

Visual analog scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Second intervention group: composition of 50% ethanol extract of propolis and nanohydroxy apatite

**Category**

Treatment - Drugs

**2****Description**

First intervention group: 50% ethanol extract of propolis

**Category**

Treatment - Drugs

### 3

#### Description

Third intervention group: placebo

#### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Yazd Shahid Sadoughi Dentistry Faculty

###### Full name of responsible person

Dr. Motahare Amiri

###### Street address

###### City

Yazd

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Shahid Sadoughi Dentistry Faculty

###### Full name of responsible person

Dr. Alireza Danesh Kazemi

###### Street address

Shahid Sadoughi Dentistry Faculty, Dahe Fajrboulvar,yazd,Iran

###### City

Yazd

###### Grant name

###### Grant code / Reference number

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

Yes

###### Title of funding source

Shahid Sadoughi Dentistry Faculty

###### 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

Shahid Sadoughi Dentistry Faculty

##### Full name of responsible person

Dr. Motahare Amiri

##### Position

Assistant professor

#### Other areas of specialty/work

#### Street address

Shahid Sadoughi Dentistry Faculty, Dahe Fajrboulvar,yazd,Iran

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Yazd

#### Postal code

#### Phone

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### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shshid Sadoughi Dentistry Faculty

##### Full name of responsible person

Dr. Motahare Amiri

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### Person responsible for updating data

#### Contact

##### Name of organization / entity

Yazd Dental University

##### Full name of responsible person

Dr. Motahare Amiri

##### Position

Assisstant professor

##### Other areas of specialty/work

#### Street address

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#### 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*