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 hypersensivity treatment : adouble 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'sexposure. 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 prosthesisor as abutmentof removable prosthesis; daily intake of anti-inflammatory drugs, analgesics, tooth desensitizer; patients with surgical periodontal ororthodontic 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 inequal 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 swipping 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 begining of study, the same soft toothbrus 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

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Motahare Amiri
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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 hypersensivity treatment : adouble blind study

Public title
The effect of propolis and nanohydroxyapatite in treatment of dentinhypersensivity.
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'sexposure. 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 prosthesisor as abutmentof removable prosthesis; daily intake of anti-inflammatory drugs, analgesics, tooth desensitizer; patients with surgical periodontal ororthodontic 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 Sadoughy 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 Hypersensivity
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
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Shahid Sadoughi Dentistry Faculty
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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