Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Antibacterial effect of Propolis as root canal medicament in necrotic teeth: A randomized single-blind clinical trial study

Protocol summary

Study aim
Antibacterial effectiveness of Propolis as root canal medicament in human necrotic teeth
Design
Clinical trial with 2 groups of Propolis or Calcium hydroxide; there are 20 teeth in each group which are randomly located and the study is single blinded.
Settings and conduct
Patient who referred to Endodontics Clinic of Mashhad dental school One canal necrotic teeth with apical peridontitis
Participants/Inclusion and exclusion criteria
Patients who has at least one necrotic, one canal tooth with apical peridontitis Teeth with calcified pulp chamber and patients who receive antibiotics now
Intervention groups
Propolis or Calcium hydroxide are placed in the root canals of one canal necrotic teeth with apical peridontitis
Main outcome variables
Calcium hydroxide, Propolis, Antibacterial effect

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180417039337N1**
Registration date: **2018-09-29, 1397/07/07**
Registration timing: **retrospective**

Last update: **2018-09-29, 1397/07/07**
Update count: **0**
Registration date
2018-09-29, 1397/07/07

Registrant information
Name
Armita Rouhani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-08-23, 1397/06/01
Expected recruitment end date
2018-09-23, 1397/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Antibacterial effect of Propolis as root canal medicament in necrotic teeth: A randomized single-blind clinical trial study

Public title
Antibacterial effect of Propolis in necrotic teeth
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referring to Mashhad Faculty of Dentistry One canal teeth Teeth with necrotic pulp Teeth with chronic apical periodontitis
Exclusion criteria:
Calcified teeth patients with immune-suppresive diseases Taking antibiotic and antifungal drugs before treatment Teeth that in not isolated with rubber dam
Age

From **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using randomization table

Blinding (investigator's opinion)

Single blinded

Blinding description

Given that Propolis and Calcium hydroxide have different appearance and physical properties, the operator can not be blind. In this study the patient, microbiologist, and data analyzer are blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad Faculty of Dentistry

Street address

Faculty of Dentistry, Azadi SQ.

City

Mashhad

Province

Razavi Khorasan

Postal code

9179775133

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

961243

Health conditions studied

1

Description of health condition studied

necrosis of pulp

ICD-10 code

k04.1

ICD-10 code description

k04.1

Primary outcomes

1

Description

measuring microbial load in each tooth using CFU (colony forming units)

Timepoint

The beginning of the study (before the intervention) and 7 days after the intervention

Method of measurement

Microbial culture and colony forming units count

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: use of propolis (Production of Razi Vaccine & Serum Research Institute with concentration determined by MIC and MBC measured in this study) as an intracanal medicament

Category

Treatment - Drugs

2

Description

Control group: Use of calcium hydroxide (Golchadent - Iran) as an intracanal medicament

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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http://v-research.mums.ac.ir/index.php/moaven/manages

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
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Position
professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Because in similar situations only the article had public availability, in this case another decision has not been made yet.

Study Protocol
No - There is not 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