

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9501

Email address

rouhania@mums.ac.ir

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-suppressive diseases Taking antibiotic and antifungal drugs before treatment Teeth that in not isolated with rubber dam

Age

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

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

negar aminzadeh

Street address

Mashhad Faculty of Dentistry , Azadi SQ.

City

Mashhad

Province

Razavi Khorasan

Postal code

9179775133

Phone

+98 51 3882 9501

Email

negar.aminzade44@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad Faculty of Dentistry , Azadi SQ.

City

Mashhad

Province

Razavi Khorasan

Postal code

9179775133

Phone

+98 51 3841 2081

Fax

+98 51 3882 3251

Email

tafaghodim@mums.ac.ir

Web page address

<http://v-research.mums.ac.ir/index.php/moaven/manager>

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

saeed moradi

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Faculty of Dentistry , Azadi SQ.

City

Mashhad

Province

Razavi Khorasan

Postal code

9179775133

Phone

+98 51 3882 9501

Email

moradis@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Armita Rouhani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Azadi SQ., Faculty of Dentistry

City

Mashhad

Province

Razavi Khorasan

Postal code

9179775133

Phone

+98 51 3882 9501

Fax

Email

rouhania@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

negar aminzadeh

Position

post graduate student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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City

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Province

Razavi Khorasan

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9179775133

Phone

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Email

negar.aminzade44@gmail.com

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