

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of antimicrobial efficacy and flare up incidence of Allium Sativum L. extract as an endodontic irrigant following instrumentation in infected teeth: a single blind clinical trial

Protocol summary

Study aim

Evaluation of antimicrobial efficacy and flare up incidence of Allium Sativum L. extract as an endodontic irrigant following instrumentation in infected teeth: a single blind clinical trial

Design

Clinical trial with 2 group of Allium Sativum L. extract or sodium hypochlorite; there are 20 teeth in each group which are randomly allocated and the study is single blinded

Settings and conduct

Patients who referred to the endodontic clinic of Mashhad dental school one canal necrotic teeth with chronic apical periodontitis

Participants/Inclusion and exclusion criteria

Patients who have at least one necrotic, one canal tooth with chronic apical periodontitis are included in this study. Teeth with calcified pulp chamber, teeth that can not be isolated with rubber dam, patients with immune-suppressive diseases and patients taking antibiotic before or during treatment are excluded in this study.

Intervention groups

Intervention group: use of Allium Sativum L. extract as an endodontic irrigant. Control group: use of sodium hypochlorite 5.25% as an endodontic irrigant.

Main outcome variables

antibacterial effect; pain; swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181103041534N1**

Registration date: **2018-12-24, 1397/10/03**

Registration timing: **retrospective**

Last update: **2018-12-24, 1397/10/03**

Update count: **0**

Registration date

2018-12-24, 1397/10/03

Registrant information

Name

Samaneh Hajizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3867 3916

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-09, 1397/08/18

Expected recruitment end date

2018-12-09, 1397/09/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of antimicrobial efficacy and flare up incidence of Allium Sativum L. extract as an endodontic irrigant following instrumentation in infected teeth: a single blind clinical trial

Public title

Antimicrobial efficacy of Allium Sativum extract as endodontic irrigant

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients referring to Mashhad Faculty of dentistry
 permanent teeth one canal teeth with necrotic pulp teeth
 with chronic apical periodontitis

Exclusion criteria:

teeth with calcified pulp chamber patients with immune-
 suppressive disease taking antibiotic before or during
 treatment teeth that can not be isolated with rubber dam

AgeFrom **10 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget 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 Allium Sativum L. extract and sodium
 hypochlorite 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

Azadi SQ

City

Mashhad

Province

Razavi Khorasan

Postal code

9179775133

Approval date

2018-09-12, 1397/06/21

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

necrosis of pulp

ICD-10 code

K04.1

ICD-10 code description

Necrosis of pulp

Primary outcomes**1****Description**

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

Timepoint

The beginig of the study (before intervention) and 3 days
 after the interventuon

Method of measurement

Microbial culture and colony forming units count

Secondary outcomes

empty

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

Intervention group: use of Allium sativum L. as an
 endodontic irrigant

Category

Treatment - Drugs

2**Description**

Control group: use of sodium hypochlorite az an
 endodontic irrigant

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad Faculty of Dentistry

Full name of responsible person

Samane Hajizadeh

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Mashhad Faculty of Dentistry, Azadi SQ

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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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
Jamilel Ghodduji
Position
Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

Jamilel Ghodduji

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Samaneh Hajizadeh

Position

Post graduate student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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