

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

hajizadehs941@mums.ac.ir

##### 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

**Age**From **10 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**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 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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smnhajizadeh@gmail.com

## 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  
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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**  
Jamilel Ghodduji  
**Position**  
Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

#### Contact

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Jamilel Ghodduji

#### Position

Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

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## Person responsible for updating data

#### Contact

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#### Position

Post graduate student

#### Latest degree

Medical doctor

#### Other areas of specialty/work

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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