Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 periodontists are included in this study Teeth with calcified pulp chamber, teeth that can not be isolated with rubber dam, patients with immune-suppresive diseases and patients taking antibiotic befor or during trearment 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)

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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-suppresive 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
IR.MUMS.DENTISTRY.REC.1397.003

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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Web page address
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
Jamilel Ghoddusi

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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Name of organization / entity
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Samaneh Hajizadeh

Position
Post graduate student

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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