

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of pain after single-visit root canal treatment following different irrigants; randomized clinical trial

Protocol summary

Study aim

Comparison of pain after single-visit root canal treatment following different irrigant

Design

Clinical trial with parallel, randomized groups. The randomization method is simple and using RandList1.2 software. 51 people of each groups will be divided into three 17 people groups. Irrigants serum, sodium hypochlorite and chlorhexidine will be used for the each groups of tooth type during root canal treatment. Finally, the amount of pain in the groups will be measured and compared.

Settings and conduct

The study will be performed in the endodontics department of Tabriz Dental School. 153 patients will be selected. In order to evaluate the effects of different detergents, sterile serum, sodium hypochlorite and chlorhexidine gluconate will be used in different groups. Pain intensity will be recorded daily in VAS form for one week. Participants as well as the evaluating researcher are unaware of the type of treatment performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.No facial paraesthesia 2.No history of trauma 3.Absence of pathological envelope during probing 4.Completing the ethical questionnaire and willingness to participate in the study Exclusion criteria: 1.Pain for no reason before treatment 2.Pregnancy and lactation 3.Severe periodontal disease 4.Overfilling the root canal space 5.Teeth that can not be separated by a rubber barrier 6.Root canal calcification 7. Roots and teeth that are not suitable for further restoration 8. Use drugs or special medication

Intervention groups

Group 1: Use of sterile serum as a irrigant Group 2: Use of 2.5% sodium hypochlorite as a irrigant Group 3: Use of chlorhexidine gluconate 2% as a irrigant

Main outcome variables

The amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101108005141N8**

Registration date: **2020-11-24, 1399/09/04**

Registration timing: **retrospective**

Last update: **2020-11-24, 1399/09/04**

Update count: **0**

Registration date

2020-11-24, 1399/09/04

Registrant information

Name

Shahriar Shahi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41133559659

Email address

shahis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2020-10-06, 1399/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pain after single-visit root canal treatment following different irrigants; randomized clinical trial

Public title

Comparison of pain after root canal treatment following different irrigants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Systemically healthy patient Patient age 65_18 years No allergy to chlorhexidine, sodium hypochlorite No facial paresthesia not taking any painkillers 6 hours before treatment not taking any medication that interferes with anesthesia No history of trauma Absence of pathological pocket during probing Completion of the ethical questionnaire and willingness to participate in the study The patient who needs root canal treatment

Exclusion criteria:

Pain for no reason before treatment Pregnancy and lactation Severe periodontal disease Overfilling the root canal space Teeth that can not be isolated by a rubber dam Root canal calcification Roots and teeth that are not suitable for further restoration Use of a specific drug or medication

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **153**

Randomization (investigator's opinion)

Randomized

Randomization description

153 patients selected in this study will be selected by available sampling method. The study will be performed in three different groups on necrotic - symptomatic and asymptomatic molars . In order to investigate the effects of different irrigants in each of the dental groups (necrotic - asymptomatic - symptomatic) 51 people in each group will be placed randomly using Rand list 1.2 software in three groups with 17 people each . In each of these 17 groups, one of the irrigans chlorhexidine - sodium hypochlorite or serum will be used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

3rd floor, No2 Central Building , Tabriz University of Medical Sciences, ,Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2020-08-31, 1399/06/10

Ethics committee reference number

IR.TBZMED.REC.1399.562

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02.5

ICD-10 code description

Caries with pulp exposure

Primary outcomes

1

Description

The amount of pain

Timepoint

Daily for a week

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Using sterile serum as a irrigant during root canal treatment in symptomatic, asymptomatic, necrotic molars.The volume of irrigant between each instrumentation will be 2 ml

Category

Treatment - Other

2

Description

Intervention group 2: Use 2.5% sodium hypochlorite as a irrigant during root canal treatment in symptomatic, asymptomatic , necrotic molars. The volume of irrigant between each instrumentation will be 2 ml

Category

Treatment - Other

3

Description

Intervention group 3: Use chlorhexidine gluconate 2% as a irrigant during root canal treatment in symptomatic, asymptomatic , necrotic molars. The volume of irrigant between each instrumentation will be 2 ml

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Shahriar Shahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Shahriar Shahi

Position

Professor of Endodontics

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be 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