

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Pulpotomy versus root canal therapy to treat irreversible pulpitis in human permanent molars: A multicenter randomized non-inferiority trial.

Protocol summary

Summary

Abstract: Aim: The purpose of this randomized, open labelled, parallel group, multicenter non-inferiority trial is to compare the outcome measures of root canal therapy and pulpotomy treatment in terms of clinical and radiographical success and also postoperative pain relieving in human permanent molar teeth diagnosed with irreversible pulpitis. **Method and Materials:** Six hundred patients will participate based on established criteria, and each has a clinical signs and symptoms of an irreversible pulpitis. The patients are randomly allocated into three arms: 1- One-visit root canal therapy (ORCT: n=200) as reference treatment, 2- pulpotomy with a new endodontic cement (PNEC: n=200), and 3- pulpotomy with Mineral Trioxide Aggregate (PMTA: n=200) as new treatments. The patients will record degree of pain intensity at the baseline and following treatment on a 7-day visual analogue scale (VAS, rated 0-9). Clinical and radiographical success on a 24 month's frame will be assessed. The data will be analyzed statistically with One- and 2-way ANOVA.

General information

Acronym

VPT

IRCT registration information

IRCT registration number: **IRCT138706131191N1**

Registration date: **2008-10-11, 1387/07/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2008-10-11, 1387/07/20

Registrant information

Name

Saeed Asgary

Name of organization / entity

Iranian Center for Endodontic Research

Country

Iran (Islamic Republic of)

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+98 21 2241 3897

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Recruitment status

Recruitment complete

Funding source

shaheed beheshti medical university office for oral health
- ministry of health and medical education

Expected recruitment start date

2008-04-01, 1387/01/13

Expected recruitment end date

2008-09-30, 1387/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pulpotomy versus root canal therapy to treat irreversible pulpitis in human permanent molars: A multicenter randomized non-inferiority trial.

Public title

vital pulp therapy to treat irreversible pulpitis

Purpose

Treatment

Inclusion/Exclusion criteria

-Diagnostic criteria: 1) Patient reports pain of endodontic origin 2) Diagnosis of irreversible pulpitis -Eligibility criteria: 1) Molar tooth 2) Patient chooses to have tooth extraction for pain relief 3) Age 9-65 years 4) Both gender 5) The patient had read and thoroughly

understood the questionnaires 6) Written informed consent -Exclusion criteria: 1) Moderate or severe periodontitis 2) None restorable tooth 3) Internal or external root resorption 4) Root canal calcification 5) No bleeding after access cavity preparation 6) Analgesic taken within the last 4 h 7) Active systemic disease 8) The patient was pregnant or nursing 9) History of opioid addiction or abuse 10) Temporary residency

Age

From **9 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **600**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

vital pulp therapy to treat irreversible pulpitis(VPT)

Secondary trial Id

NCT00748280

Registration date

2008-09-08, 1387/06/18

Ethics committees

1

Ethics committee

Name of ethics committee

Iran Center for Dental Research

Street address

5th floor , shahid beheshti dental school, Evin ,Tehran

City

Tehran

Postal code

19839613113

Approval date

empty

Ethics committee reference number

8600

Health conditions studied

1

Description of health condition studied

vital pulp therapy to treat irreversible pulpitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

clinical success of pulpotomy

Timepoint

from treatment time to 24 month after treatment

Method of measurement

clinical examination (percussion,soft tissue palpation ,observation of periapical soft tissue)

2

Description

radiographical success of pulpotomy

Timepoint

from treatment time to 24 month after treatment

Method of measurement

periapical radiography(periodontal tissue health)

Secondary outcomes

1

Description

Pain value

Timepoint

before treatment ,6 hours after treatment ,12 hours after treatment and after that every 12 hours to 7th day.

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

one-visit root canal therapy

Category

empty

2

Description

pulpotomy with mineral trioxide aggregate

Category

empty

3

Description

pulpotomy with new endodontic cement

Category
empty

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid beheshti medical science university
Full name of responsible person
Dr.Taheri
Street address
City
Tehran

2

Recruitment center

Name of recruitment center
Iran medical science university
Full name of responsible person
Dr.Rahnama
Street address
City
Tehran

3

Recruitment center

Name of recruitment center
Shiraz medical science university
Full name of responsible person
Dr.Dehghan
Street address
City
Shiraz

4

Recruitment center

Name of recruitment center
Mashhad medical science university
Full name of responsible person
Dr.Heravi
Street address
City
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5

Recruitment center

Name of recruitment center
Shahid sadooghi medical science university
Full name of responsible person
Dr.Fotoohi
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran Center of Endodontics Research center
Full name of responsible person
Dr.saeed asgary
Street address
5th floor , shahid beheshti dental school, Evin ,Tehran
City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran Center of Endodontics Research center

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity
office for oral health-ministry of health and medical education
Full name of responsible person
Street address
City

Grant name

Grant code / Reference number

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

Title of funding source

office for oral health-ministry of health and medical education

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
endodontics research center
Full name of responsible person

mohammad jafar eghbal

Position

wise president(research)/endodontist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty