Clinical Trial Protocol
Iranian Registry of Clinical Trials
01 Jul 2019

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

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

None

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

Country

Iran (Islamic Republic of)

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
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<thead>
<tr>
<th>Recruitment center</th>
<th>Name of recruitment center</th>
<th>Full name of responsible person</th>
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<tr>
<td>Iran medical science university</td>
<td>Iran medical science university</td>
<td>Dr. Rahnama</td>
<td>5th floor, shahid beheshti dental school, Evin, Tehran</td>
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<td>Shiraz medical science university</td>
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<tr>
<td>Dr. Saeed Asgary</td>
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Person responsible for general inquiries

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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
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Data Dictionary
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