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: empty
Registration date
2008-10-11, 1387/07/20
Registrant information
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Iranian Center for Endodontic Research
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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
  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 (percusion, 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
  priapical 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
Country
Iran (Islamic Republic of)

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Iran Center of Endodontics Research center

Full name of responsible person
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5th floor , shahid beheshti dental school, Evin ,Tehran

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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
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
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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
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

3
Sponsor
Name of organization / entity
Shiraz medical science university

Full name of responsible person
Dr.Dehghan

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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
Shiraz medical science university

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

4
Sponsor
Name of organization / entity
Mashhad medical science university

Full name of responsible person
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Street address
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Iran (Islamic Republic of)

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

Title of funding source
Mashhad medical science university

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

5
Sponsor
Name of organization / entity
Shahid sadooghi medical science university

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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