Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of post operative pain in necrotic pulp using two different instrumention techniques : A Randomized Clinical Trial

Protocol summary

Summary

Aim of this study is comparison of postoperative pain using Reciproc and RaCe files in necrotic pulp.inclusion criteria : age over 18-year-old ; no systemic disease necrotic pulp without pain before treatment ; normal or periapical lesion less than 2.5mm ; sensivity on percussion ; no sensivity on palpation ; restorable, no sinus tract or apical abscess or facial cellulite exclusion criteria : age lower than 18-year-old ; systemic disease ; pregnancy,milking mother,allergy to lidocaine ,normal pulp, pulpit,normal periapical or periapcal lesion greater than 2.5mm ; failure in anesthesia ; bleeding after coronal access ; intake of analgesics 48 -72 hours before treatment ; intake of cortone one week before treatment ; sensivity on palpation.patients were selected from referred patients to Tabriz Dental College,endodontic department, from 22/10/2014 till 22/10/2015. 90 mandibular molar teeth with necrotic pulp were randomized in two 45-case group and underwent root canal therapy: group A :Race Rotary File , group B :Reciproc File.After determining working length of tooth each group were underwent cleaning and shaping according to manufacture instructions and then after confirming Master Cone with radiography ,the canal dried with paper cone and filled with sealer AH26 and gutta percha with lateral compaction technique.Finally access cavity filled with zonalin. The intensity of pain was documented using a visual analogue scale on 4th, 12th, 24th, 48th, and 72nd hours and at week 1 post operation and compared between the two groups and the forms were analysed by blind person.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012126137N1**
Registration date: **2016-02-24, 1394/12/05**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-02-24, 1394/12/05

Registrant information

Name
Aila Hasani
Name of organization / entity
Tabriz University of Medical Sciences, Dentistry College
Country
Iran (Islamic Republic of)
Phone
+98 41 3335 5965
Email address
zandv@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-10-22, 1393/07/30

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of post operative pain in necrotic pulp using two different instrumention techniques : A Randomized Clinical Trial

Public title

finding a technique for root canal therapy with less pain after therapy

Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria : age over 18-year-old ; no systemic disease necrotic pulp without pain before treatment ; normal or periapical lesion less than 2.5mm ; sensivity on percussion ; no sensivity on palpation ; restorable, no sinus tract or apical abscess or facial cellulite exclusion criteria : age lower than 18-year-old ; systemic disease ; pregnancy,milking mother,allergy to lidocaine ,normal pulp, pulpit,normal periapical or periapcal lesion greater than 2.5mm ; failure in anesthesia ; bleeding after coronal access ; intake of analgesics 48 -72 hours before treatment ; intake of cortone one week before treatment ; sensivity on palpation
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz Medical University
Street address
Abresan _ Daneshgah square _ Tabriz University
City
Tabriz
Postal code
Approval date
2015-10-26, 1394/08/04
Ethics committee reference number
TBZMED.REC.1394.659

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
post operative pain
Timepoint
4th, 12th, 24th, 48th, and 72nd hours and at week 1 postoperation
Method of measurement
a visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
45 root canal of mandibular molar underwent preparation and shaping using RaCe Rotary file and then post operative pain will underwent analyses .
Category
Treatment - Other

2

Description
45 root canal of mandibular molar underwent preparation and shaping using Reciprocating file and then post operative pain will underwent analyses .
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Dental College
Full name of responsible person
Aila Hasani , post graduate student of endodontic
Street address
Tabriz University of Medical Siceinces, Daneshgah Square, Abresan st.
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Aila Hasani
Street address
Tabriz University of Medical Sciences , Daneshgah Square , Abresan st.
City
Tabriz
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
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
Tabriz Dental University
Full name of responsible person
Mohammad Samiei
Position
Research Assistant
Other areas of specialty/work
Street address
Daneshgah square_ Tabriz medical university
City
Tabriz
Postal code
Phone
+98 41 3335 5967
Fax
Email
dr.hasani67@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Dentistry College
Full name of responsible person
vahid zand
Position
Endodontist
Other areas of specialty/work
Street address
Tabriz Medical university , Daneshgah Square , Abresan st.
City
Tabriz
Postal code
Phone
+98 41 3335 5967
Fax
Email
dr.hasani67@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz Dentistry College
Full name of responsible person
Aila Hasani
Position
Post graduate student of endodontic
Other areas of specialty/work
Street address
Tabriz Medical university, Daneshgah Square , Abresan st.
City
Tabriz
Postal code
Phone
+98 41 3335 5967
Fax
Email
dr.hasani67@gmail.com
Web page address
tbzmed.ac.ir

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