

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of post operative pain in necrotic pulp using two different instrumentation 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, pulpitis, normal periapical or periapical 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 instrumentation 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 ; sensitivity on percussion ; no sensitivity 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, pulpitis, normal periapical or periapical 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 ; sensitivity 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 undergo 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 undergo 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 Sciences, Daneshgah Square, Abresan st.

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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.

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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

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

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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