Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Two Different Rotary Instruments (RaCe, ProTaper) on Postoperative Pain in Teeth with Asymptomatic Irreversible Pulpitis: A Randomized Clinical Trial

Protocol summary

Summary

Comparison of two different rotary instruments (RaCe, ProTaper) on postoperative pain in teeth with asymptomatic irreversible pulpitis: A Randomized Clinical Trial Inclusion criteria: Teeth with asymptomatic irreversible pulpitis; normal radiographic periapical appearance. Exclusion criteria: Subjects under 20 years of age and over 50 years of age; any systemic diseases; nursing and pregnant women; allergies to lidocaine; reversible pulpitis; symptomatic irreversible pulpitis; pulpal necrosis; PDL widening; periapical radiolucency; teeth with fixed partial dentures; use of any analgesics for at least 12 hours before enrollment in the study. A total of 78 patients (male or female) 20-50 years of age with a first or second mandibular molar with asymptomatic irreversible pulpitis will enrolled in the study. Patients will undergo treatment randomly by choosing a packet in which the type of the instrument is written as follows A: ProTaper and B: RaCe groups (39 patients in each group). After initial working length record, in each group the instruments will be used to prepare canals in a manner according to the manufacturer instructions. The patients will be asked to mark their pain using visual analogue scale at 4-, 12-, 24-, 48- and 72-hour and 1-week postoperative intervals. Finally data will be analyzed. The patients will be blinded to the types of the instruments used (single blind).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503035141N3**
Registration date: **2015-06-13, 1394/03/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-13, 1394/03/23

Registrant information

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Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-06-10, 1394/03/20

Expected recruitment end date

2015-07-29, 1394/05/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Two Different Rotary Instruments (RaCe, ProTaper) on Postoperative Pain in Teeth with Asymptomatic Irreversible Pulpitis: A Randomized Clinical Trial

Public title

Pain Measurement after Root Canal Treatment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Subjects 20-50 years of age; no systemic diseases; teeth with asymptomatic irreversible pulpitis; normal radiographic periapical appearance. Exclusion criteria: Subjects under 20 years of age and over 50 years of age; any systemic diseases; nursing and pregnant women; allergies to lidocaine; reversible pulpitis; symptomatic irreversible pulpitis; pulpal necrosis; PDL widening; periapical radiolucency; presence of internal or external resorption; teeth with fixed partial dentures; no bleeding after pulp exposure; use of any analgesics for at least 12 hours before enrollment in the study.

Age

From **74 years** old to **43 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Since the patients will be blinded to the types of the instruments used, this study was considered a single-blind one. Patients will undergo treatment randomly by choosing a packet in which the type of the instrument is written (there will be 78 packets).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Floor3- Centeral Building No2-Tabriz University of Medical Sciences- Golgasht St

City

Tabriz

Postal code

Approval date

2015-04-27, 1394/02/07

Ethics committee reference number

TBZMED.REC.1394.47

Health conditions studied

1

Description of health condition studied

Asymptomatic Irreversible Pulpitis

ICD-10 code

K04.0

ICD-10 code description

Irreversible Pulpitis

Primary outcomes

1

Description

Intensity Postoperative Pain after Root Canal Treatment

Timepoint

at 4-, 12-, 24-, 48- and 72-hour and 1-week after root canal treatment

Method of measurement

Visual Analogue Scale(VAS)

Secondary outcomes

1

Description

The Number of Analgesic Tablets Taken

Timepoint

at 4-, 12-, 24-, 48- and 72-hour and 1-week after root canal treatment

Method of measurement

Record by patient

Intervention groups

1

Description

ProTaper rotary instruments (Dentsply-Maillefer, Ballaigues, Switzerland) will be used for the root canal treatment procedures with the crown-down technique based on manufacturer's instructions. Each file will be used to prepare only 8 root canals. The root canals will be obturated with gutta-percha and AH26 sealer (Dentsply,De Trey,Konstanz,Germany).

Category

Other

2

Description

RaCe rotary instruments (FKG Dentaire, Switzerland) will be used for the root canal treatment procedures with the crown-down technique based on manufacturer's instructions. Each file will be used to prepare only 8 root

canals. Root canals will be obturated with gutta-percha and AH26 sealer(Dentsply,De Trey,Konstanz,Germany).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontic department-Faculty of Dentistry-Tabriz University of Medical Sciences

Full name of responsible person

Asghari Kalejahi Vahideh

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Endodontic department-Faculty of Dentistry- Tabriz University of Medical Sciences-Golgasht St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Rashidi Mohammad Reza

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Floor3-Central buildingNo2-Tabriz University of Medical Sciences -Golgasht 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

Vice chancellor for research, 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

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Rashidi Mohammad Reza

Position

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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