Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Effects of Manual and Rotary Instrumentation Techniques on Postoperative Pain in Mandibular Molar Teeth with Asymptomatic Irreversible Pulpitis: A Prospective Randomized Clinical Trial

Protocol summary

Summary

The primary aim of the present study is to compare the effect of root canal preparation with hand and rotary files on the severity of postoperative endodontic pain in teeth with Asymptomatic Irreversible Pulpitis.The design of this study is randomized and double blind. The inclusion criteria consist of healthy subjects requiring endodontic treatment on mandibular first or second molars with asymptomatic irreversible pulpits , normal periapical radiographic view and no use of analgesics for at least 12 hours before the endodontic treatment. Patients under 18 years old , have sinus tract, periapical abscesses and the patients whose local anesthesia last for more than 4 hours, are excluded from the study.The sample size was estimated based on the results of a pilot study calculated at 96 subjects, with 48 in each group, by considering the results of the pilot study and at α= 0.05 and a study power of 80%. Subjects are randomly categorized into tow groups: A: rotary RaCe files B:manual k-files. After determination the working lengths and preparation procedure for each group, the root canals are dried with paper points and obturating is done during the same session with the lateral compaction technique using cold gutta-percha and AH Plus sealer. Postoperative pain is evaluated with visual analog scale . The picture is given to each patient and its completion technique , is explained. Data on pain is recorded by the patients at 4-, 8-, 12-, 24- and 48-hour and 1-week internals.The present study is carried out in 5 months duration in the Department of Endodontic, Tabriz Faculty of Dentistry on patients referring to the Department. Comparison of pain severity , number of painless patients and use of analgesics in each time periods between two groups is done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041521780N1**
Registration date: **2015-05-23, 1394/03/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-23, 1394/03/02

Registrant information

Name

Bita Talebzadeh

Name of organization / entity

Endodontic Department of Dental Faculty of Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

Expected recruitment start date

2015-03-06, 1393/12/15

Expected recruitment end date

2015-08-06, 1394/05/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Manual and Rotary Instrumentation Techniques on Postoperative Pain in Mandibular Molar Teeth with Asymptomatic Irreversible Pulpitis: A Prospective Randomized Clinical Trial

Public title
Comparison of Manual and Rotary Instrumentation Techniques on Postoperative Pain
Purpose
Other
Inclusion/Exclusion criteria
Inclusion Criteria: Age over than 18 years old ; With pulpal status of asymptomatic irreversible pulpitis ; Normal periradicular status radio graphically ; Systemically healthy ; Conducive to restoration ; Needing selective one-visit treatment ; Presence of lip sign after administration of anesthesia ; Presence of bleeding after exposure of the pulp ; Teeth with 3 or 4 root canals ; No drug use or use of 400 mg of ibuprofen during the 24-hour postoperative interval ; Straight with not difficult to access SLA. Exclusion Criteria: Age Under than 18 years old ; Healthy pulpal status or reversible pulpitis or symptomatic irreversible pulpitis or necrosis ; Widening of PDL or radiolucency or radiopacity in the origin of periradicular ; Systemic disease ; Breast-feeding ; Pregnancy ; Hypersensitivity to lidocaine ; Impossible to restore the teeth ; Presence of a crown before the procedure ; Needing 2-visit treatment or any extra procedure such as incision and drainage ; Absence of lip sign after administration of anesthesia ; Absence of bleeding after exposure of the pulp ; Teeth with 1 or 2 root canals ; The presence of a difficult root canal anatomy (root canals with extreme curvatures (over 30°) and C-shape canals) ; Internal or external resorption ; Teeth with open apices ; Radiographically untraceable canal path or any accident or complication occurring during treatment (calcified canals, inability to achieve apical patency in any canal) ; Use of analgesics 12 hours before treatment ; Use more than 400 mg of ibuprofen during the 24-hour postoperative interval or any dose after 24 hours ; Severe labial or lingual malpositioning of teeth making it difficult to access SLA ; More teeth needing RCT on the same side.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **96**
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
Ethics of Tabriz University of Medical Sciences
Street address
Vice Chancellor Research.Third floor.Number 2 central building.Golgasht street.Tabriz Medical University.
City
Tabriz
Postal code
Approval date
2015-03-05, 1393/12/14
Ethics committee reference number
5/4/12154

Health conditions studied

1

Description of health condition studied
Postoperative Pain
ICD-10 code
E18,E19,E2
ICD-10 code description
XVIIIInjury, poisoning and certain other consequences of external causes XX External causes of morbidity and mortality XXI Factors influencing health status and contact with health services

Primary outcomes

1

Description
Postoperative Pain
Timepoint
4,8,12,24,48 hour and one week intervals
Method of measurement
Use of Visual Analog Scale(VAS) picture

Secondary outcomes

1

Description
Use of Analgestic Drugs (ibuprofen 400 mg)
Timepoint
In first 24 hours until one week(use or not use of analgestic drugs in first 24 hours until one week)
Method of measurement
Ask the pationts

2

Description
The number of painless pationts
Timepoint
4,8,12,24,48 hours and one week intervals
Method of measurement
Use of Visual Analog Scale(VAS) picture

Intervention groups

1

Description
First intervention group: Instrumentation and treatment of mandibular first and second molar canals with rotary RaCe system by 7 RaCe rotary files and crowndown technique according to manufacturers instructions in one visit.
Category
Treatment - Surgery

2

Description
Second intervention group:Treatment and instrumentation of mandibular first and second molars canals with manual k-flexofiles and k-files by stepback technique in one visit.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Endodontic Department of
Faculty of Dentistry of Tabriz University of Medical Sciences
Full name of responsible person
Saied Rahimi,Endodontics Profissor
Street address
Second floor.Third enteranse.Golgasht Ave.Endodontic Department.Faculty of Dentistry.Tabriz University of Medical Sciences .Tabriz.Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor Research of Dental Faculty of Tabriz University of Medical Sciences
Full name of responsible person
Mohamadreza Rashidi,Vice Chancellor Research of Dental Faculty of Tabriz University of Medical Scien
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Vice Chancellor Research.Third floor.Number 2 central building.Golgasht Street.Tabriz Medical University.Tabriz.Iran
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Grant name
124202
Grant code / Reference number
10506000
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor Research of Dental Faculty of 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
Endodontic Department of Faculty of Dentistry of Tabriz University of Medical Sciences
Full name of responsible person
Saied Rahimi
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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