Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of post-operative pain after root canal preparation using Mtwo (NiTi) rotary and hand K-File in single visit enododontic treatment

Protocol summary

Summary

This study aims to compare the pain after root canal preparation using Mtwo(NiTi) rotary files and hand K-Files in single-visit endodontic treatment. The Inclusion criteria includes: single canaled teeth needing root canal therapy because of irreversible pulpitis with moderate to severe pain (VAS 4-10). The Exclusion criteria includes: teeth with acute apical periodontitis; teeth with necrotic pulp; patient presenting with abscess or cellulitis. This study is performed on the patients from the Department of Endodontics, Dentistry School, Babol University of Medical Sciences. A sample size of sixty patients is considered. After selected, the patients are randomly assigned into two groups; Group A: root canals are prepared with Mtwo rotary files (Mtwo, VDW, Germany). Group B: root canals are prepared with hand K-files using step-back method. VAS (Visual Analogue Scale) is explained for the patients and the patients are asked to quantify preoperative pain on VAS scale. After the treatment is done the patient is instructed to quantify the pain intensity on VAS scale in 4, 8, 12 and 24 hour intervals if he or she feels pain, and return after 48 hours for assessment. The subjects of this study are not aware of which treatment method they receive, thus this is a single-blinded study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031216973N1**
Registration date: **2015-06-02, 1394/03/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-02, 1394/03/12

Registrant information

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Scienses

Expected recruitment start date

2014-11-21, 1393/08/30

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of post-operative pain after root canal preparation using Mtwo (NiTi) rotary and hand K-File in single visit enododontic treatment

Public title

Comparison of the pain after root canal therapy between the traditional method and a modernized method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: single canaled teeth needing root canal therapy because of irreversible pulpitis with moderate to

severe pain (VAS 4-10) Exclusion criteria: teeth with acute apical periodontitis; teeth with necrotic pulp; patient presenting with abscess or cellulitis

Age
From **14 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol University of Medical Sciences

Street address
University Sq., Ganj Afrooz Ave.

City
Babol

Postal code

Approval date
2015-02-07, 1393/11/18

Ethics committee reference number
305121/ژ/پ

Health conditions studied

1

Description of health condition studied
Irrevesible pulpitis

ICD-10 code
K04.0

ICD-10 code description
Pulpitis

Primary outcomes

1

Description
Pain

Timepoint
4 hours, 8 hours, 12 hours, 24 hours after invention

Method of measurement
VAS scale

Secondary outcomes

empty

Intervention groups

1

Description
Root canals prepared with Mtwo (NiTi) rotary files(VDW, Germany)

Category
Treatment - Other

2

Description
Root canals prepared with hand K-Files(Mani, Japan)

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Dentistry School

Full name of responsible person
Mohammad Saeed Eram

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Felestin Ave., Velayat Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Headship of Dental Material Study Center

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Felestin Ave., Velayat Sq.

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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
Babol 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

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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