

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

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

Name

Mohammad Kashefinejad

Name of organization / entity

Faculty of Dentistry, Babol University of Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

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 endodontic 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/پ/ز

Health conditions studied

1

Description of health condition studied

Irreversible 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

Street address

Felestin Ave., Velayat Sq.

City

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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

Street address

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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**Contact****Name of organization / entity**

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Web page address**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