

# 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

Iran (Islamic Republic of)

##### Phone

+98 11 1229 1408

##### Email address

m.kashefi@mubabol.ac.ir

#### 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

Babol

## 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

Felestin Ave., Velayat Sq.

##### City

Babol

#### 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**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Kashefinejad

**Position**

Endodontics dept. professor

**Other areas of specialty/work****Street address**

University Sq., Ganj Afrooz Ave.

**City**

Babol

**Postal code****Phone**

+98 11322914089

**Fax****Email**

m.kashefi@mubabol.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Mohammad Saeed Eram

**Position**

Dental student

**Other areas of specialty/work****Street address**

Felestin Ave., Velayat Sq.

**City**

Babol

**Postal code****Phone**

+98 11322914089

**Fax****Email**

saeederam69@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Mohammad Saeed Eram

**Position**

Dental student

**Other areas of specialty/work****Street address**

Felestin Ave., Velayat Sq.

**City**

Babol

**Postal code****Phone**

00

**Fax****Email**

saeederam69@yahoo.com

**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*