

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of the effect of root canal preparation using four single endodontic file techniques on postoperative pain, a randomized clinical trial

#### Protocol summary

##### Summary

The aim of this study is to compare the pain following single file root canal preparation by using Race , Neoniti and Mtwo files and two conventional method by using Race and Mtwo files. three In this double blind study, sixty three consented patients having the inclusion criteria will be randomly into three groups of 21 according to the type of tooth and their number of root canals. We will use minimization technique for randomization. After local anesthesia injection (Lidocaine with 1/80000 epinephrine,Daroupakhsh, Tehran, Iran), access cavities will be prepared and rubberdam isolation will be accomplished. Working length determination will be done by an electronic apex locator (Root ZX, J Morita, Tokyo, Japan) and confirmed by radiographic imaging. Root canal preparation will be accomplished by one of the following three instrumentation systems in a single file technique. a. Neoniti A1 25.08 (Neolix, France) b. RACE 25.06 (FKG Dentaire, La-Chaux-de-Fonds, Switzerlan) c. Mtwo 25.06 (Sweden and Martina, Padua, Italy) 5.25% sodium hypochloride will be used for irrigation during instrumentation. Afterwards the smear layer removal will be accomplished by 17%EDTA (Calasept, Nordiska Dental, Angelholm, Sweden) and 2% chlorhexidine liquid (Calasept, Nordiska Dental, Angelholm, Sweden) will be used as the final irrigant. Subsequently obturation will be done with gutta-percha and AH26 sealer using a lateral compaction technique. At the end of the first appointment a single dose of 400 mg Ibuprofen (Gelofen®, Jabberebne Hayyan, Tehran ,Iran) will be taken by the patient. Nine other capsules will also be provided to them. Postoperative pain levels will be recorded by a blind operator every 6h up to 7 days.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201506167963N2**

Registration date: **2015-09-22, 1394/06/31**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-09-22, 1394/06/31

##### Registrant information

###### Name

Mohsen Aminsobhani

###### Name of organization / entity

Tehran University of Medical Sciences, Faculty Of Dentistry

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8895 0567

###### Email address

maminsobhani@irimc.org

##### Recruitment status

###### Recruitment complete

##### Funding source

Neolix company AJA University of Medical Sciences

##### Expected recruitment start date

2015-04-01, 1394/01/12

##### Expected recruitment end date

2015-12-31, 1394/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of root canal preparation using four single endodontic file techniques on postoperative pain, a randomized clinical trial

## Public title

Effect of different root canal preparation techniques on the after treatment pain experienced by patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: consented patients between the ages of 15 to 55 years; having no systemic disease; needing primary root canal treatment; an asymptomatic premolar or molar tooth; having either asymptomatic irreversible pulpitis or pulp necrosis without any apical pathosis

Exclusion criteria: having symptoms prior to treatment initiation; root canal curvature more than 25 (measured by Schneider's method); having any systemic disease; requiring endodontic retreatment; having any periapical pathosis

## Age

From 15 years old to 55 years old

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 63

## 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

AJA University of Medical Sciences

##### Street address

Etemad zadeh avenue, Fatemi st.

##### City

Tehran

##### Postal code

#### Approval date

2015-05-22, 1394/03/01

#### Ethics committee reference number

IR.AJAUMS.REC.1394.12

## Health conditions studied

### 1

#### Description of health condition studied

asymptomatic irreversible pulpitis

#### ICD-10 code

K04.0

#### ICD-10 code description

Pulpitis

### 2

#### Description of health condition studied

asymptomatic necrosis of the pulp

#### ICD-10 code

K04.1

#### ICD-10 code description

Necrosis of pulp

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

6 hour intervals after treatment up to 7 days

#### Method of measurement

numerical rating scale (NRS)

## Secondary outcomes

### 1

#### Description

number of consumed analgesics

#### Timepoint

6 hour time intervals

#### Method of measurement

number of tablets

## Intervention groups

### 1

#### Description

Mtwo 25.06

#### Category

Treatment - Devices

### 2

#### Description

Full sequence Mtwo

#### Category

Treatment - Devices

### 3

#### Description

Neoniti A1 25.08

#### Category

Treatment - Devices

### 4

#### Description

RACE 25.06

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Dentistry, AJA University of Medical Sciences

##### Full name of responsible person

Mohsen Aminsobhani

##### Street address

Shahid Gohari St, Moalem St, Shariati St

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

AJA University of Medical Sciences

##### Full name of responsible person

Kamran Azma

##### Street address

Shahid Etemadzade St, West Fatemi St

##### City

Tehran

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

AJA University of Medical Sciences

##### Proportion provided by this source

##### 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*

### 2

#### Sponsor

##### Name of organization / entity

Neolix Company

##### Full name of responsible person

Xavier Rolland

##### Street address

11 Avenue Raoul Vadepied, 53600 Châtres-la-Forêt, France

##### City

CHÂTRES-LA-FORET

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Neolix Company

##### Proportion provided by this source

##### 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

AJA University of Medical Sciences

##### Full name of responsible person

Mohsen Aminsobhani

##### Position

Endodontist

##### Other areas of specialty/work

##### Street address

#1593 Didgah alley, North Kargar St, Tehran, Iran

##### City

Tehran

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##### Phone

+98 21 8895 0567

##### Fax

##### Email

maminsobhani@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

AJA University of Medical Sciences

##### Full name of responsible person

Mohsen Aminsobhani

##### Position

Endodontist

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

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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*