# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jul 2026

## Comparison of pain intensity after root canal therapy with three different instrumentation technique

### Protocol summary

**Study aim**
Comparison of severity of pain after three protaper, neolix, reciproc systems in endodontic treatment of patients admitted to Babol dental clinic in year 97

**Design**
This randomized clinical trial was performed and the sample size was calculated using the same articles as well as by a 90-member formula. Randomly, they were divided into three groups of three, and in each group

**Settings and conduct**
Patients referring to the special clinic of Babol dental school in randum were divided into 3 groups in the first group (n: 30) root canal therapy using rotated protaper files and in the second group (n: 30) using neolix files and in The third group (n: 30) will treat roots using reciproc files.First, for all patients with desirable anesthesia with lidocaine 2%, with epinephrine 1/80000, after the completion of the isolation access cavity with the ribbed, the length of the canals is determined using the root zx apex locator and radiography confirmed. Each group will be treated differently, and normal saline and sodium hypochlorite washers will be used. Finally, the canals are dried with paper syringe and obturation will be done by lateral condensation using Gutta Perca and AH26 sealer, and the tooth will be temporarily restored with dressing and the VAS questionnaire will be delivered to the patients. After five days, the questionnaire will be delivered to me

**Participants/Inclusion and exclusion criteria**
inclusion criteria:Patients aged between 20-65 years with irreversible pulpitis for upper and lower jaw molars;exclusion criteria: Patients with systemic conditions, with necrosis teeth or reversible pulpitis

**Intervention groups**
All 90 patients referred to three groups with three neolix, protaper, wave one reciprocal are treated

**Main outcome variables**
Using this study, a suitable system for root canal therapy with less pain is identified

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190514043592N1**
Registration date: **2019-07-09, 1398/04/18**
Registration timing: **retrospective**

Last update: **2019-07-09, 1398/04/18**
Update count: **0**

**Registration date**
2019-07-09, 1398/04/18

**Registrant information**

**Name**
Sanaz Solati

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 11 3452 6770

**Email address**
s.solati@mubabol.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-01-21, 1397/11/01

**Expected recruitment end date**
2019-02-20, 1397/12/01

**Actual recruitment start date**
2019-01-21, 1397/11/01

**Actual recruitment end date**
2019-03-16, 1397/12/25

**Trial completion date**
2019-03-17, 1397/12/26

**Scientific title**

Comparison of pain intensity after root canal therapy with three different instrumentation technique

**Public title**
Comparison of pain after root canal therapy
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients aged 20 to 65 years Patients with maxillary or mandibular molar that have irreversible pulpitis Patients with low to moderate visual analog scale
**Exclusion criteria:**
Patients who have had previous root canal therapy Patients who receive corticosteroids Patients who have been using analgesics for 12 hours before root canal therapy Patients who have a tooth root, calcification, or internal or external resorption or open apex or anatomical complexity (Curve greater than 25 degrees) Patients whose teeth have any of the swelling and abscess , sensitivity to percusion and periodontal disease Patients who are pregnant Dissatisfaction patients to participate in the study
**Age**
From **20 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **90**
Actual sample size reached: **90**
**Randomization (investigator's opinion)**
N/A
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
The Ethics Committee of Babol University of Medical Sciences
**Street address**
Babol University of Medical Sciences, Street Ganj Afrooz, Babol city
**City**
Babol
**Province**
Mazandaran
**Postal code**
4717647745
**Approval date**
2019-01-19, 1397/10/29
**Ethics committee reference number**
IR.MUBABOL.HRI.REC.1397.240

## Health conditions studied

### 1

**Description of health condition studied**
Irreversible pulpitis
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Pain
**Timepoint**
4,24,48,72,96 hours after root canal therapy
**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: In this group, root canal therapy of maxillary and mandibular molars was performed using a Neolix rotary system ( 1.5 N / cm torque and 300-500 rpm speed).
**Category**
Treatment - Devices

### 2

**Description**
Intervention group:In this group, root canal therapy of maxillary and mandibular molars was performed using Reciprocal wave one system ( 4 N / cm torque and 350 rpm speed).
**Category**
Treatment - Devices

### 3

**Description**
Control group: In this group, root canal therapy of maxillary and mandibular molars was performed using protaper rotary system ( 2.5 N / cm torque and 350-450

rpm speed).

**Category**
Treatment - Devices

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Special Clinic of Babol School of Dentistry

**Full name of responsible person**
Sanaz Solati

**Street address**
Babol University of Medical Sciences, Street Ganj Afrooz, Babol city

**City**
Babol

**Province**
Mazandaran

**Postal code**
4717647745

**Phone**
+98 11 3219 9592

**Fax**
+98 11 3219 0181

**Email**
info@mubabol.ac.ir

**Web page address**
https://www.mubabol.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Babol University of Medical Sciences

**Full name of responsible person**
Dr Reza Ghadimi

**Street address**
Babol University of Medical Sciences, Street Ganj Afrooz, Babol city

**City**
Babol

**Province**
Mazandaran

**Postal code**
4717647745

**Phone**
+98 11 3219 9592

**Fax**
+98 11 3219 0181

**Email**
info@mubabol.ac.ir

**Web page address**
http://www.mubabol.ac.ir

**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**
30

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Babol University of Medical Sciences

**Full name of responsible person**
Sanaz Solati

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Dentistry

**Street address**
Aparteman toohid,ro be roye felestin 1 , khiaban felestin , khiaban Amir mazandarani, sari

**City**
Sari

**Province**
Mazandaran

**Postal code**
4851648659

**Phone**
+98 11 3452 6770

**Fax**

**Email**
s.solati@mubabol.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Babol University of Medical Sciences

**Full name of responsible person**
Sanaz Solati

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Dentistry

**Street address**
Aparteman toohid,ro be roye felestin 1 , khiaban felestin , khiaban Amir mazandarani, sari

**City**
Sari

**Province**

Mazandaran

**Postal code**

4851648659

**Phone**

+98 11 3452 6770

**Fax**

**Email**

s.solati@mubabol.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Sanaz Solati

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Aparteman toohid,ro be roye felestin 1 , khiaban felestin , khiaban Amir mazandarani, sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4851648659

**Phone**

+98 11 3452 6770

**Fax**

**Email**

s.solati@mubabol.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Because of the privacy of patients

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Using the placement of a study in bookshops as well as submitting articles and publications in the Medical Journal

**When the data will become available and for how long**

Immediately after printing the results

**To whom data/document is available**

All medical colleagues

**Under which criteria data/document could be used**

No condition is considered

**From where data/document is obtainable**

Academic Library and Magazines

**What processes are involved for a request to access data/document**

Attend a library or ask for visits from reputable medical journals

**Comments**