Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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

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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

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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
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

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

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Person responsible for scientific inquiries

Contact

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Babol University of Medical Sciences

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Person responsible for updating data

Contact

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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