# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of the mean post operative pain after manual and rotary instrumentation for root canal treatment of single rooted teeth with irreversible pulpitis and normal periapex

## Protocol summary

**Study aim**

The present study is aimed at recording the average intensity of pain experienced by the patients after root canal procedure through rotary devices which are not used in common practice by the dentists in our community and comparing it with older techniques such as manual hand files which are more commonly used.

**Design**

In this non blinded randomized control trial subjects were divided into two interventional groups by lottery method. There were 30 subjects in each. The patients were asked to mark their pain on a Numeric pain intensity scale at 6-, 12-, 24- and 48- hour postoperative intervals.

**Settings and conduct**

Out-patients in the department of Operative dentistry, Rehman College of Dentistry, Peshawar

**Participants/Inclusion and exclusion criteria**

The inclusion criteria were patients of both gender of age between 20 to 50`years, incisors and canines with irreversible pulpitis, periodontally sound tooth, with no systemic diseases, no radiographic changes on periapical radiograph and restorable teeth. Excluded were subjects who had taken pain medication 12 hours prior to the treatment. Subjects unable to understand the consent and the procedure itself.

**Intervention groups**

In the manual instrumentation group the cleaning and shaping of the root canals was done by NiTi K-files. In the rotary instrumentation group cleaning and shaping of the root canals was done by HyflexNiTi rotary system. In order to keep equal apical diameter, the final apical preparation in both groups was kept similar.. The patients were asked to mark their pain on a Numeric pain intensity scale at 6-, 12-, 24- and 48- hour postoperative intervals.

**Main outcome variables**

Pain perceived by the subject at given time post operative intervals.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230713058771N1**
Registration date: **2023-07-24, 1402/05/02**
Registration timing: **retrospective**

Last update: **2023-07-24, 1402/05/02**
Update count: **0**

**Registration date**

2023-07-24, 1402/05/02

**Registrant information**

**Name**

Asim Qureshi

**Name of organization / entity**

Ayub medical and dental college

**Country**

Pakistan

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+92 340 9053423

**Email address**

asim@ayubmed.edu.pk

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-01-01, 1400/10/11

**Expected recruitment end date**

2023-06-30, 1402/04/09

**Actual recruitment start date**

2022-01-01, 1400/10/11

**Actual recruitment end date**

2022-12-30, 1401/10/09

**Trial completion date**

2022-12-30, 1401/10/09

**Scientific title**

Comparison of the mean post operative pain after manual and rotary instrumentation for root canal treatment of single rooted teeth with irreversible pulpitis and normal periapex

**Public title**

Comparison of the mean post operative pain after manual and rotary instrumentation for root canal treatment of single rooted teeth with irreversible pulpitis and normal periapex

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Incisors and canines with irreversible pulpitis Periodontally sound tooth No systemic diseases No radiographic changes on periapical radiograph Restorable teeth

**Exclusion criteria:**

Patients with mental or physical disability Patient who has taken analgesic within the last 12 hours Teeth with malposition Teeth with fixed partial dentures

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After proper history taking , investigations and formal consent. Subject was considered in one of our two groups by random allocation (lottery method). In this method each subject was asked to pick a sealed envelope out of the total 60. Each sealed envelope marked which group the subject will be put in. This was not concealed from the subject. This randomization was done by non- probability consecutive sampling.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethical committee at Rehman college of Dentistry

**Street address**

Plot #5 B2 phase V Hayatabad, Peshawar

**City**

Peshawar

**Postal code**

25000

**Approval date**

2020-07-21, 1399/04/31

**Ethics committee reference number**

EC-REFNO; 20-07-15

## Health conditions studied

**1**

**Description of health condition studied**

Irreversible pulpitis of single rooted teeth

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

**1**

**Description**

Pain perceived by subject after the root canal treatment

**Timepoint**

6-, 12-, 24- and 48- hour postoperative intervals.

**Method of measurement**

Numeric pain intensity scale (handed to patient in printed form)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Control group: cleaning and shaping by manual instruments

**Category**

Treatment - Devices

**2**

**Description**

Intervention group: cleaning and shaping by rotary instruments

**Category**

Treatment - Devices

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Operative department Rehman college of dentistry
**Full name of responsible person**
Dr. Nida Gul Sepah
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## Sponsors / Funding sources

**1**

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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**
Rehman college of dentistry
**Proportion provided by this source**
15
**Public or private sector**
Private
**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**
Rehman college of dentistry
**Full name of responsible person**
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**Position**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**
Data collected for the primary outcome measure only

**When the data will become available and for how long**
Once published it will be available .

**To whom data/document is available**
People in academic institutions only

**Under which criteria data/document could be used**
Corresponding author will address this on an individual case bases . As requested by any inquire

**From where data/document is obtainable**
Person to contact for scientific quires.
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**What processes are involved for a request to access data/document**
Applicant needs to provide the reason for the document and how it might be used.

**Comments**