

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

##### Phone

+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

**Street address**

Plot 5 B2 phase V Hayatabad

**City**

Peshawar

**Postal code**

25000

**Phone**

+92 345 4589890

**Email**

nidasepah@gmail.com

Rehman college of dentistry  
**Full name of responsible person**

Dr. Nida Gul Sepah

**Position**

Resident

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

**Street address**

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**Province**

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Rehman college of dentistry

**Full name of responsible person**

Dr. Nida Gul Sepah

**Street address**

Plot 5 B2 phase 5 hayatabad

**City**

Peshawar

**Postal code**

25000

**Phone**

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**Email**

nidasepah@gmail.com

**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**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ayub medical and dental college

**Full name of responsible person**

Asim Qureshi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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Riaz house hill street opposite hotel one

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**Province**

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**Phone**

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**Fax**

**Email**

asimovtm@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Rehman college of dentistry

**Full name of responsible person**

Dr. Nida Gul Sepah

**Position**

Resident

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

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**Province**

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**Postal code**

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**Email**

nidasepah@gmail.com

## 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.

asimovtm@gmail.com

**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**