

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

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Postal code

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Phone

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rehman college of dentistry

Full name of responsible person

Dr. Nida Gul Sepah

Street address

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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

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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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Resident

Latest degree

Bachelor

Other areas of specialty/work

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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.

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