

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of post instrument pain after cleaning and shaping using Gentefile(Tornado) system and comparing with Mtwo rotary system(double blinded clinical trial).

Protocol summary

Study aim

The aim of this study is to evaluate post instrument pain after cleaning and shaping using Gentefile(Tornado) system and comparing with Mtwo system.

Design

The patients are divided in 2 groups randomly by using a random number table. Each patient is assigned a 4-digit code, if the end digit on the right is 2,7,9, the patient is in Mtwo group, and if the final digit is 3,5,6, the patient is in Gentlefile group. The total sample size is 30 and the phase does not apply in this study.

Settings and conduct

The study population is people who visit Dr Reza Hatam office (endodontist) for molar root canal treatment. In this study, patients are evaluated for inclusion and exclusion criteria. Blindness is performed for the pain assessor and the patient. They have no information about the cleaning and shaping system. The assessor calls patients at specified intervals after treatment and asks them about post-treatment pain and taken analgesics(Ibuprofen 400mg).

Participants/Inclusion and exclusion criteria

Inclusion criteria is age 18 to 60 years old. Exclusion criteria is internal and external resorption, periodontal disease, retreatment cases, necrotic tooth, tooth with calcified canals, immature roots, systemic problems which have contraindication for root canal treatment.

Intervention groups

patients are randomly divided into 2 groups. Each group is treated with one of the Gentlefile(Tornado), Mtwo system. Each patient is assigned a code. Codes are kept in envelopes. The patient randomly selects one of the envelopes before entering. The specialist chooses the cleaning and shaping system based on the codes. The treatment steps in all 2 groups are exactly the same. The only difference is in the cleaning and shaping system used.

Main outcome variables

The amount of post endodontic treatment pain

General information

Reason for update

In this study, it was decided to compare three study groups and three interventions. These interventions included cleaning and shaping the root canal with Mtwo rotary system, cleaning and shaping the root canal with Rotaper Gold rotary system, and cleaning and shaping the root canal with Gentlefile (Tornado) rotary system. Unfortunately, due to the corona epidemic and the decrease in the number of patients referred to the dental office and On the other hand, due to the lack of equipment for cleaning and shaping the root canal with Protaper Gold system, the group of researchers decided to remove the Protaper Gold group at the discretion of the Research Council of the School of Dentistry. Patient treatment is ongoing for the remaining two interventions. However, the intervention of cleaning and shaping the root canal with the Protaper Gold rotary system has been eliminated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200707048043N1**
Registration date: **2020-09-08, 1399/06/18**
Registration timing: **prospective**

Last update: **2020-12-19, 1399/09/29**

Update count: **1**

Registration date

2020-09-08, 1399/06/18

Registrant information

Name

Kiana Salavati

Name of organization / entity

Country

Iran (Islamic Republic of) Phone +98 83 3843 3075 Email address kianasalavati@yahoo.com	envelopes. The envelopes are arranged randomly and the patient selects them. The total sample size is 45 and the phase does not apply in this study.
Recruitment status Recruitment complete Funding source	Blinding (investigator's opinion) Double blinded Blinding description In this study both the patient and the outcome assessor will be blinded. The patients won't have any information about cleaning and shaping system. Pain assessor will have no information about division of patients in groups.
Expected recruitment start date 2020-09-30, 1399/07/09 Expected recruitment end date 2021-01-30, 1399/11/11 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	Placebo Not used Assignment Parallel Other design features
Scientific title Evaluation of post instrument pain after cleaning and shaping using Gentefile(Tornado) system and comparing with Mtwo rotary system(double blinded clinical trial).	Secondary Ids empty
Public title Evaluation of post instrument pain using Gentefile(Tornado) system and comparing with Mtwo system. Purpose Supportive Inclusion/Exclusion criteria Inclusion criteria: age between 18 to 60 years old Exclusion criteria: external root resorption internal root resorption periodontal disease retreatment cases necrotic tooth tooth with calcified canals immature roots systemic problems which have contraindication for root canal treatment such as uncontrolled diabetes ,osteoradio necrosis ,uncontrolled blood pressure Age From 18 years old to 60 years old Gender Both Phase N/A Groups that have been masked - Participant - Outcome assessor	Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Kermanshah university of medical sciences Street address Ethics Committee, Kermanshah Medical Sciences Research Center, Shahid Beheshti Blvd, Kermanshah City Kermanshah Province Kermanshah Postal code 6714869914 Approval date 2020-08-21, 1399/05/31 Ethics committee reference number IR.KUMS.REC.1399.474 Health conditions studied 1 Description of health condition studied post endodontic treatment pain ICD-10 code ICD-10 code description
Sample size Target sample size: 30 Randomization (investigator's opinion) Randomized Randomization description A random number table is used for randomization. Each patient is assigned a 4-digit code, if the end digit on the right is 2,7,9, the patient is in the Mtwo group, and if the final digit is 3,5,6, the patient is in the Gentlefile group. All codes are recorded on paper and stored in specific	Primary outcomes 1 Description patient's pain levels in Visual Analogue Scale Timepoint The pain is evaluated 2,4,8,12,24,48,72 hours and one week after treatment. Method of measurement Visual Analogue Scale

Secondary outcomes

1

Description

Number of Ibuprofen 400 mg taken by the patient

Timepoint

Every 6 hours after endodontic treatment

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

The first comparison group is the group in which the cleaning and shaping process is done with the Gentlefile (Tornado) system.

Category

Treatment - Devices

2

Description

The second comparison group is the group in which the cleaning and shaping process is done with the Mtwo system.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontist` office

Full name of responsible person

Reza Hatam

Street address

Number 2, First floor, Diplomat building, The first 30 meters st, 22 Bahman st

City

Kermanshah

Province

Kermanshah

Postal code

6713954658

Phone

+98 83 3839 2053

Email

reza_hatam@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Hatam

Street address

Endodontics Department, Faculty of Dentistry, Dr. Shariati St, Kermanshah

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Kermanshah

Province

Kermanshah

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6713954658

Phone

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Email

rhatam@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

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

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Hatam

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Department of Endodontics, Faculty of Dentistry, In front of the Post Office, Dr. Shariati St, Kermanshah

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Kermanshah

Province

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54658-67139

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+98 83 3727 7030

Email

reza_hatam@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

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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

Yes - There is 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

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

Title and more details about the data/document

After completing the study and deidentifying the information of the participants, the main outcome of the study will be shared through Kermanshah University of Medical Sciences.

When the data will become available and for how long

Documents will be available 6 months after publication.

To whom data/document is available

Documents will be available to researchers working at academic institutions.

Under which criteria data/document could be used

Researchers can use the documents of the current study to conduct systematic review and meta-analysis studies.

From where data/document is obtainable

To access the documents, you can go to the following postal address: Postal Code: 671584714, Room 4, First floor, Vice Chancellor for Research and Technology, Building No. 2, Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard, Kermanshah or Or by telex: 083-38393158 or Email address: src_research@kums.ac.ir.

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

Documents can be accessed by referring to the mentioned addresses and introducing the relevant university institution.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Hatam

Position

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Latest degree

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Other areas of specialty/work

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