

# 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)                                                                                                                                                                                                                                                                                                                 | 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.                                                                                                            |
| <b>Phone</b><br>+98 83 3843 3075                                                                                                                                                                                                                                                                                                           | <b>Blinding (investigator's opinion)</b><br>Double blinded                                                                                                                                                                                                      |
| <b>Email address</b><br>kianasalavati@yahoo.com                                                                                                                                                                                                                                                                                            | <b>Blinding description</b><br>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. |
| <b>Recruitment status</b><br><b>Recruitment complete</b>                                                                                                                                                                                                                                                                                   | <b>Placebo</b><br>Not used                                                                                                                                                                                                                                      |
| <b>Funding source</b>                                                                                                                                                                                                                                                                                                                      | <b>Assignment</b><br>Parallel                                                                                                                                                                                                                                   |
| <b>Expected recruitment start date</b><br>2020-09-30, 1399/07/09                                                                                                                                                                                                                                                                           | <b>Other design features</b>                                                                                                                                                                                                                                    |
| <b>Expected recruitment end date</b><br>2021-01-30, 1399/11/11                                                                                                                                                                                                                                                                             | <b>Secondary Ids</b><br>empty                                                                                                                                                                                                                                   |
| <b>Actual recruitment start date</b><br>empty                                                                                                                                                                                                                                                                                              | <b>Ethics committees</b>                                                                                                                                                                                                                                        |
| <b>Actual recruitment end date</b><br>empty                                                                                                                                                                                                                                                                                                | <b>1</b>                                                                                                                                                                                                                                                        |
| <b>Trial completion date</b><br>empty                                                                                                                                                                                                                                                                                                      | <b>Ethics committee</b>                                                                                                                                                                                                                                         |
| <b>Scientific title</b><br>Evaluation of post instrument pain after cleaning and shaping using Gentefile(Tornado) system and comparing with Mtwo rotary system(double blinded clinical trial).                                                                                                                                             | <b>Name of ethics committee</b><br>Ethics committee of Kermanshah university of medical sciences                                                                                                                                                                |
| <b>Public title</b><br>Evaluation of post instrument pain using Gentefile(Tornado) system and comparing with Mtwo system.                                                                                                                                                                                                                  | <b>Street address</b><br>Ethics Committee, Kermanshah Medical Sciences Research Center, Shahid Beheshti Blvd, Kermanshah                                                                                                                                        |
| <b>Purpose</b><br>Supportive                                                                                                                                                                                                                                                                                                               | <b>City</b><br>Kermanshah                                                                                                                                                                                                                                       |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                                                                                                                        | <b>Province</b><br>Kermanshah                                                                                                                                                                                                                                   |
| <b>Inclusion criteria:</b><br>age between 18 to 60 years old                                                                                                                                                                                                                                                                               | <b>Postal code</b><br>6714869914                                                                                                                                                                                                                                |
| <b>Exclusion criteria:</b><br>external root resorption internal root resorption<br>periodontal disease retreatment cases necrotic tooth<br>tooth with calcified canals immature roots systemic problems which have contraindication for root canal treatment such as uncontrolled diabets ,osteoradio necrosis ,uncontrolled blood presure | <b>Approval date</b><br>2020-08-21, 1399/05/31                                                                                                                                                                                                                  |
| <b>Age</b><br>From <b>18 years</b> old to <b>60 years</b> old                                                                                                                                                                                                                                                                              | <b>Ethics committee reference number</b><br>IR.KUMS.REC.1399.474                                                                                                                                                                                                |
| <b>Gender</b><br>Both                                                                                                                                                                                                                                                                                                                      | <b>Health conditions studied</b>                                                                                                                                                                                                                                |
| <b>Phase</b><br>N/A                                                                                                                                                                                                                                                                                                                        | <b>1</b>                                                                                                                                                                                                                                                        |
| <b>Groups that have been masked</b>                                                                                                                                                                                                                                                                                                        | <b>Description of health condition studied</b><br>post endodontic treatment pain                                                                                                                                                                                |
| <ul style="list-style-type: none"> <li>Participant</li> <li>Outcome assessor</li> </ul>                                                                                                                                                                                                                                                    | <b>ICD-10 code</b>                                                                                                                                                                                                                                              |
| <b>Sample size</b><br>Target sample size: <b>30</b>                                                                                                                                                                                                                                                                                        | <b>ICD-10 code description</b>                                                                                                                                                                                                                                  |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                | <b>Primary outcomes</b>                                                                                                                                                                                                                                         |
| <b>Randomization description</b><br>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    | <b>1</b>                                                                                                                                                                                                                                                        |
|                                                                                                                                                                                                                                                                                                                                            | <b>Description</b><br>patient`s pain levels in Visual Analogue Scale                                                                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                            | <b>Timepoint</b><br>The pain is evaluated 2,4,8,12,24,48,72 hours and one week after treatment.                                                                                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                            | <b>Method of measurement</b><br>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

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6713954658

#### Phone

+98 83 3727 7030

#### 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

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

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##### Phone

+98 83 3727 7030

##### Email

reza\_hatam@yahoo.com

## Person responsible for scientific 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**

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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**

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

**City**

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**Province**

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**Postal code**

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