

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 2026

### Investigation Response to Pulp Sensitivity Tests after Full Pulpotomy in Permanent Mandibular Teeth with Symptomatic Irreversible Pulpitis

#### Protocol summary

##### Study aim

The present study aims to investigate the response to pulp sensitivity tests after complete pulpotomy in mandibular permanent teeth with symptomatic irreversible pulpitis.

##### Design

The clinical trial has an intervention group and is conducted on 36 patients.

##### Settings and conduct

The present study is conducted in clinics and private offices in Ilam city.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age range 16-35 years - adult permanent mandibular molars with deep or very deep occlusal/proximal caries with marked irreversible pulpitis - After providing complete and informative explanations about Root Canal therapy (RCT) and complete pulpotomy, its advantages and disadvantages and success and failure rates in this type of treatment, complete pulpotomy was performed with the patient's consent. If the treatment fails, RCT treatment is used as an alternative treatment. Exit criteria: - Caries in the buccal and lingual area - History of trauma and orthodontic treatment and therapy and special parafunctional habits - Mandibular molar teeth with proximal occlusal decay with diagnosis of necrosis and reversible pulpitis

##### Intervention groups

In the present study, electric pulp test and cold test are used to check the success rate of complete pulpotomy treatment after 12 months. First intervention: electrical test, second intervention: cold test

##### Main outcome variables

suggestion an effective pulp sensitivity test in the field of complete pulpotomy in mandibular permanent teeth with symptomatic irreversible pulpitis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230525058289N1**

Registration date: **2023-06-14, 1402/03/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-06-14, 1402/03/24**

Update count: **0**

##### Registration date

2023-06-14, 1402/03/24

##### Registrant information

##### Name

mehdi ziagham ahvaz

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3222 8541

##### Email address

mehdiziagham@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-11, 1402/03/21

##### Expected recruitment end date

2023-07-12, 1402/04/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            |                                                                                                                                                         |                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Investigation Response to Pulp Sensitivity Tests after Full Pulpotomy in Permanent Mandibular Teeth with Symptomatic Irreversible Pulpitis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                            | Ilam University of Medical Sciences campus, Banganjab, Research Blvd, Ilam                                                                              |                        |
| <b>Public title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Investigation Response to Pulp Sensitivity Tests after Full Pulpotomy in Permanent Mandibular Teeth with Symptomatic Irreversible Pulpitis | <b>City</b>                                                                                                                                             | ilam                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            | <b>Province</b>                                                                                                                                         | Ilam                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            | <b>Postal code</b>                                                                                                                                      | 6939177143             |
| <b>Purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Treatment                                                                                                                                  | <b>Approval date</b>                                                                                                                                    | 2023-05-08, 1402/02/18 |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                            | <b>Ethics committee reference number</b>                                                                                                                |                        |
| <b>Inclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                            | IR.MEDILAM.REC.1402.025                                                                                                                                 |                        |
| Age range 16-35 years adult permanent mandibular molars with deep or very deep occlusal/proximal caries with marked irreversible pulpitis After providing complete and informative explanations about RCT treatment and complete pulpotomy, its advantages and disadvantages and success and failure rates in this type of treatment, complete pulpotomy was performed with the patient's consent. In case of treatment failure, RCT treatment was used as an alternative treatment.                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                            | <b>Health conditions studied</b>                                                                                                                        |                        |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                            | <b>1</b>                                                                                                                                                |                        |
| Buccal and lingual caries History of trauma and orthodontic and restorative treatments as well as specific parafunctional habits Mandibular molar teeth with proximal occlusal caries with diagnosis of necrosis and reversible pulpitis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                            | <b>Description of health condition studied</b>                                                                                                          |                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            | In this study, patients with adult permanent teeth with deep or very deep occlusal/proximal caries with symptomatic irreversible pulpitis are examined. |                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            | <b>ICD-10 code</b>                                                                                                                                      |                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            | K04.0                                                                                                                                                   |                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            | <b>ICD-10 code description</b>                                                                                                                          |                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                            | Pulpitis                                                                                                                                                |                        |
| <b>Primary outcomes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                            |                                                                                                                                                         |                        |
| <b>1</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                            |                                                                                                                                                         |                        |
| <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                            |                                                                                                                                                         |                        |
| Success and failure of full pulpotomy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                            |                                                                                                                                                         |                        |
| <b>Timepoint</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                            |                                                                                                                                                         |                        |
| Success was assessed 12 months after full pulpotomy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                            |                                                                                                                                                         |                        |
| <b>Method of measurement</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                            |                                                                                                                                                         |                        |
| - Examination of radiographs, clinical examination (using cold and electrical tests)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                            |                                                                                                                                                         |                        |
| <b>Secondary outcomes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                            |                                                                                                                                                         |                        |
| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                            |                                                                                                                                                         |                        |
| <b>Intervention groups</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                            |                                                                                                                                                         |                        |
| <b>1</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                            |                                                                                                                                                         |                        |
| <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                            |                                                                                                                                                         |                        |
| Intervention group: In this study, two electric and cold tests were used to check the success of full pulpotomy treatment. First intervention: Electric test: In the electric pulp test, the opposite and treated tooth is removed with a cotton roll. The lip clip is placed in the corner of the patient's mouth. The tip of the electrode is covered with water-based gel and is placed between the gingival edge and the occlusal edge of the buccal surface of the mandibular molar tooth, and the contact of the electrode with the free edge of the gingiva is prevented. Finally, the patient is asked to raise his hand if he feels any emotion. The response is recorded as "Reply Received" or "No Response". The second intervention: Cold test: The cold test is performed using a cooling spray of tetrafluoroethene 2,1,1,1 and size 2 cotton, which is |                                                                                                                                            |                                                                                                                                                         |                        |

applied in the same position as the electric electrode on the buccal surface of the tooth. This test is performed by an endodontist for 5 seconds.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Clinics and private offices in Ilam city

**Full name of responsible person**

Dr Amin Kheytri

**Street address**

3rd Floor, Razi Complex, Adib Alley, South Saadi, Ilam

**City**

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**Province**

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ilam University of Medical Sciences

**Full name of responsible person**

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Ilam University of Medical Sciences campus,  
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**City**

Ilam

**Province**

Ilam

**Postal code**

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info@medilam.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ilam 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**

Ilam University of Medical Sciences

**Full name of responsible person**

Mehdi Ziagham Ahwaz

**Position**

Dentistry student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

No. 21, between Nabii and Razavi, Mohammadian St,  
South Shariati,

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ilam University of Medical Sciences

**Full name of responsible person**

Mehdi Ziagham Ahwaz

**Position**

Dentistry student

**Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ilam University of Medical Sciences

**Full name of responsible person**

Mehdi Ziagham Ahwaz

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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**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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 of patients after full pulpotomy in mandibular permanent teeth with symptomatic irreversible pulpitis

**When the data will become available and for how long**

The access period starts 1 year after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Other statistical analyzes are allowed in these data.

**From where data/document is obtainable**

Send a message to the following email to receive the data mehdiziagham@yahoo.com

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

Send email and register request

**Comments**