

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the analgesic effect of Meloxicam and Ibuprofen on post endodontic pain

#### Protocol summary

##### Study aim

Comparison of the analgesic effect of Meloxicam and Ibuprofen on post endodontic pain

##### Design

Twenty-two patients with irreversible pulp recognition and two lateral tooth (left and right), will be selected. This study is clinical trial and double blind.

##### Settings and conduct

Twenty-two patients with irreversible pulp recognition and two lateral tooth (left and right), will be selected. This study is clinical trial and double blind. This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Recognize pulpitis irreversible, Both of gender  
Exclusion criteria: Lack of cooperation

##### Intervention groups

We treat patients in Ibuprofen group by 11 tab of Ibuprofen 400 milligram (Aria, Tehran, Iran). We treat patients in Meloxicam group by 11 tab of Meloxicam 7.5 milligram (Zahravi, Tabriz, Iran).

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N109**

Registration date: **2019-04-27, 1398/02/07**

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

Last update: **2019-04-27, 1398/02/07**

Update count: **0**

##### Registration date

2019-04-27, 1398/02/07

##### Registrant information

###### Name

Fariba Farokhi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2020-01-21, 1398/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the analgesic effect of Meloxicam and Ibuprofen on post endodontic pain

##### Public title

Comparison of the analgesic effect of Meloxicam and Ibuprofen on post endodontic pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Recognize pulpitis irreversible Both of gender

**Exclusion criteria:**

Lack of cooperation

**Age**

From 20 years old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: 22

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple individual randomization with random number table in division of groups in two groups A and B. Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment: Numbered drug containers

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee Arak University Of Medical Sciences

**Street address**

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

38149578558

**Approval date**

2019-01-13, 1397/10/23

**Ethics committee reference number**

IR.ARAKMU.REC.1397.284

**Health conditions studied**

1

**Description of health condition studied**

pulpitis irreversible

**ICD-10 code**

K04.0

**ICD-10 code description**

Pulpitis

**Primary outcomes**

1

**Description**

Pain

**Timepoint**

After 2 weeks

**Method of measurement**

Analog Visual scale

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: We treat patients in Ibuprofen group by 11 tab of Ibuprofen 400 milligram(Aria,Tehran,Iran).

**Category**

Treatment - Drugs

2

**Description**

Intervention group: We treat patients in Meloxicam group by 11 tab of Meloxicam 7.5 milligram(Zahravi,Tabriz,Iran).

**Category**

Treatment - Drugs

3

**Description**

Intervention group: We treat patients in Ibuprofen group by 11 tab of Ibuprofen 400 milligram(Aria,Tehran,Iran).

**Category**

Treatment - Drugs

## 4

### Description

Intervention group: We treat patients in Meloxicam group by 11 tab of Meloxicam 7.5 milligram(Zahravi,Tabriz,Iran).

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental clinic

##### Full name of responsible person

Dr Najmeh Kermani

##### Street address

Payambar Azam Complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3417 3645

##### Email

kermani@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor For Research, Arak University Of Medical Science

##### Full name of responsible person

Dr Mohammad Arjmandzadegan

##### Street address

Vice Chancellor For Research, Arak University Of Medical Science

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3417 3645

##### Email

arjmandzadegan@arakmu.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice Chancellor For Research, Arak University Of Medical

Science

##### 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

Arak University of Medical Sciences

##### Full name of responsible person

Dr Najmeh Kermani

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

##### Street address

Payambar Azam Complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3417 3505

##### Email

kermani@arakmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Najmeh Kermani

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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##### Province

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##### Postal code

3848176941

**Phone**

+98 86 3417 3505

**Email**

kermani@arakmu.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Raziye Zokaei

**Position**

Dental student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

Payambar Azam Complex, Basij square, Sardasht,  
Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3417 3505

**Email**

raziyezokaei73@yahoo.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**

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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

When we publish article in journal

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

After the article is published

**To whom data/document is available**

researcher in university

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

If there are additional questions

**From where data/document is obtainable**

Dr Kermani

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

They have to write letters to the professors and the university

**Comments**