

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparison of the effects of Naproxen, Diclofenac and Piroxicam on TMD

#### Protocol summary

##### Study aim

We aimed to compare the effect of three NSAID drugs (naproxen, diclofenac and piroxicam) on temporo-mandibular disorders (TMD).

##### Design

This randomized, triple-blind, clinical trial, was done on 104 patients aged 20-45 years with TMD. Patients were divided randomly (using the table of random numbers) to four groups to treat through Naproxen tablet, tablet of Diclofenac, Piroxicam capsule and Placebo.

##### Settings and conduct

The study was performed on 104 patients in the age range of 20 to 45 years old, who had referred to Kerman Dental School in a triple-blind randomized clinical trial. Patients were randomly divided into four groups for treatment with naproxen, diclofenac, piroxicam and placebo. Patients were unaware of the medication they were receiving. Pain was measured using the VAS index, clicking with a stethoscope, mouth opening with a cloth ruler, and sensitivity to touch. The person who evaluated the patient in the examination sessions as well as the person who analyzed the data; They did not know which treatment group the patient was in.

##### Participants/Inclusion and exclusion criteria

Pain in masticatory muscles; limitation in mouth opening; clicking sound; TMJ touch sensitivity; no systemic disease; no previous supportive treatments

##### Intervention groups

The study was performed on 104 patients and patients were divided into four groups: medication in the first group with Naproxen tablets at a dose of 500 mg, in the second group with Diclofenac tablets at a dose of 50 mg, in the third group with Piroxicam capsules at a dose of 10 mg Warm and in the fourth group was done with placebo for 10 days. In five stages, patients were evaluated for pain, click, tenderness and mouth opening which lasted six weeks.

##### Main outcome variables

Pain; clicking; AROM (Active Rate of Motion) and tenderness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210807052101N1**

Registration date: **2021-10-04, 1400/07/12**

Registration timing: **retrospective**

Last update: **2021-10-04, 1400/07/12**

Update count: **0**

##### Registration date

2021-10-04, 1400/07/12

##### Registrant information

##### Name

Shirin Abedinikoshkuiyeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3428 0031

##### Email address

dnt.s.abedini@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2015-11-22, 1394/09/01

##### Actual recruitment start date

2015-09-23, 1394/07/01

##### Actual recruitment end date

2015-12-11, 1394/09/20

##### Trial completion date

2016-04-29, 1395/02/10

##### Scientific title

Comparison of the effects of Naproxen, Diclofenac and

## Public title

Effects of naproxen, diclofenac and piroxicam on  
Mandibular joint pain

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Pain in masticatory muscles Limitation in mouth opening  
Clicking sound TMJ touch sensivity No systemic disease  
No previous supportive treatments

### Exclusion criteria:

Existence of systemic disease Receive previous  
supportive treatments

## Age

From **20 years** old to **45 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Data analyser

## Sample size

Target sample size: **104**

Actual sample size reached: **104**

## Randomization (investigator's opinion)

Randomized

## Randomization description

104 patients randomly divided to 4 groups using random number table. A set of numbers without a specific pattern or order were generated in a completely random manner and became a table. In order to use the table of random numbers, the researcher first determined the table to read the numbers from above. Numbers 26-01 for prescription of naproxen, 27-52 for diclofenac, 78-53 for piroxicam and 104-79 for Placebo were also considered. The researcher then touched one of the numbers and moved in one of the predetermined directions, recording the numbers and assigning them to different groups.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

Three groups were blind: 1. Patients about their drugs 2. A dentist who examined the patients in periodic meetings (care provider) 3. Data analyser

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Rafsanjan University of Medical Sciences

##### Street address

Shahid mofatteh AVE

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7717933777

#### Approval date

2015-05-22, 1394/03/01

#### Ethics committee reference number

139487

## Health conditions studied

### 1

#### Description of health condition studied

Temporo Mandibular Disorders

#### ICD-10 code

M26.6

#### ICD-10 code description

Temporomandibular joint disorders

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Time table for evaluation patients includes; the first assessment before starting treatment, the second assessment one week after starting treatment, the third session three weeks after therapy, the fourth evaluation five weeks after treatment and the fifth session six weeks after therapy.

#### Method of measurement

The amount of pain was measured with VAS index (visual analog scale).

### 2

#### Description

The amount of clicking

#### Timepoint

Time table for evaluation patients includes; the first assessment before starting treatment, the second assessment one week after starting treatment, the third session three weeks after therapy, the fourth evaluation five weeks after treatment and the fifth session six weeks after therapy.

#### Method of measurement

The amount of clicking sound was measured with stethoscope.

### 3

#### **Description**

The amount of tenderness

#### **Timepoint**

Time table for evaluation patients includes; the first assessment before starting treatment, the second assessment one week after starting treatment, the third session three weeks after therapy, the fourth evaluation five weeks after treatment and the fifth session six weeks after therapy.

#### **Method of measurement**

The degree of sensitivity to touch were done by touching the masticatory muscles and the joint area.

### 4

#### **Description**

The amount of opening mouth

#### **Timepoint**

Time table for evaluation patients includes; the first assessment before starting treatment, the second assessment one week after starting treatment, the third session three weeks after therapy, the fourth evaluation five weeks after treatment and the fifth session six weeks after therapy.

#### **Method of measurement**

The amount of mouth opening was measured with a cloth ruler (the distance between the upper and lower incisors at the maximum amount of mouth opening).

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The first Intervention group take Naproxen tablet 500 mg (Chemidarou, Tehran, Iran) twice a day for 10.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

The second Intervention group: Diclofenac tablet 50 mg (Shahredaru, Tehran, Iran) twice a day for 10.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

The third Intervention group: Piroxicam capsule 10 mg (Zahravi, Tehran, Iran) twice a day for 10 days.

#### **Category**

Treatment - Drugs

### 4

#### **Description**

Control group: Placebo twice a day for 10 days in the form of capsules similar to piroxicam and starch content.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Kerman University of Medical Sciences

##### **Full name of responsible person**

Ali Peimani

##### **Street address**

Dentistry Faculty of Rafsanjan University of Medical Sciences, West Mofatteh Blvd.

##### **City**

Rafsanjan

##### **Province**

Kerman

##### **Postal code**

7717933777

##### **Phone**

+98 34 3428 0038

##### **Fax**

+98 34 3428 0071

##### **Email**

alipeimani2001@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Rafsanjan University of Medical Sciences

##### **Full name of responsible person**

Ali Shamsizadeh

##### **Street address**

Vice Chancellor for Research and Technology, Rafsanjan University of Medical Sciences, Imam Ali Blvd.

##### **City**

Rafsanjan

##### **Province**

Kerman

##### **Postal code**

7717933777

##### **Phone**

+98 34 3428 0086

##### **Fax**

+98 34 3428 0097

##### **Email**

vcrt@rums.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

Yes  
**Title of funding source**  
Rafsanjan 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**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Ali Peimani  
**Position**  
Associate professor in surgery department  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Rafsanjan University of Medical Sciences, West  
Mofatteh blvd.  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7717933777  
**Phone**  
+98 34 3428 0038  
**Email**  
alipeimani2001@yahoo.com

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Ali Peimani  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Rafsanjan University of Medical Sciences, West  
Mofatteh blvd.  
**City**  
Rafsanjan

**Province**  
Kerman  
**Postal code**  
7717933777  
**Phone**  
+98 34 3428 0038  
**Email**  
alipeimani2001@yahoo.com

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Shirin Abedinikoshkuiyeh  
**Position**  
Dentist  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Rafsanjan University of Medical Sciences, West  
Mofatteh blvd.  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7717933777  
**Phone**  
+98 34 3428 0031  
**Fax**  
+98 34 3428 0008  
**Email**  
dnt.s.abedini@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to make this available  
**Study Protocol**  
Undecided - It is not yet known if there will be 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**  
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