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 sensivity; 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
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Iran (Islamic Republic of)
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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

Piroxicam on TMD

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

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Other areas of specialty/work
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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