

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of acetaminophen and ibuprofen before orthodontic treatment in reducing pain-clinical trial

Protocol summary

Summary

A total of 54 patients (ages, 18-25) participated in this study at the Ahvaz Jundishapur University of Medical Science of Dentistry's Department of Orthodontics, undergoing separator placement were enrolled in this double blind cross over trial study. Subjects randomly assigned to 1 of 2 experimental groups: A; stage 1: 400 mg starch capsule, stage 2: 650 mg acetaminophen and stage 3: 400 mg ibuprofen, B; stage 1: 400 mg starch capsule, stage 2: 400 mg ibuprofen, stage 3: 650 mg acetaminophen. All medication taken orally half hour before separator placement. Also all medications were alike in appearance and were blind to each subjects and clinician. By the end of the 3 months, each subject had received 3 treatment. Each patient's level of discomfort was assessed with a 10-cm visual analogue scale (VAS), before of placement, immediately after placement, at 2, 12 hours and at morning time of 2, 3, 4 and 5 days. The pain evaluations were made during: chewing, biting and at rest. Patients were asked to complete a questionnaire at appropriate intervals during the week after separator placement. Subjects returned to clinic after 1 week for separator removal. Inclusion criteria: 1) no debilitating systemic disease; 2) currently not using analgesics; 3) no periodontal and endodontic problems in the right down quadrants. Exclusion criteria: haven't any conditions from inclusion criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014022516746N1**

Registration date: **2014-07-20, 1393/04/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-20, 1393/04/29

Registrant information

Name

Parisa Kazemi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Ahvaz Jundishapur University of Medical Science

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of acetaminophen and ibuprofen before orthodontic treatment in reducing pain-clinical trial

Public title

Comparison of acetaminophen and ibuprofen before orthodontic treatment in reducing pain

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:1) no specific systemic disease; 2) currently not using analgesics; 3) no periodontal and endodontics problems. Exclusion criterion: the lack of any case inclusion criteria.

Age

From **18 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Postal code

61357-15794

Approval date

2013-07-27, 1392/05/05

Ethics committee reference number

ajums.REC.1392.107

Health conditions studied

1

Description of health condition studied

Orthodontic Pain

ICD-10 code

Z51.8

ICD-10 code description

Other specified medical care

Primary outcomes

1

Description

The measure of pain

Timepoint

Before of interference, Immediate after interference, 2-3 hours after interference,atthe bed time, at the morning of 2,3,4 and 5 days after interference

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Measure of pain at chewing, dental contact and at rest whit no contact

Timepoint

Before of interference, Immediate after interference, 2-3 hours after interference,atthe bed time, at the morning of 2,3,4 and 5 days after interference

Method of measurement

Questionnaire

Intervention groups

1

Description

Acetaminophen, 650 miligram oral tablet, single dose half hour before of separator placement

Category

Treatment - Drugs

2

Description

Ibuprofen, oral tablet 400 miligram, single dose half hour before separator placement

Category

Treatment - Drugs

3

Description

Placebo, oral capsul 500 miligram of starch, single dose half hour before separator placement

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school, ahvaz jundishapur university of medical science

Full name of responsible person

Mehrnaz Moradinejad

Street address

Orthodontic department, Dental School, Ahvaz
Jundishapur University of Medical Sciences, Golestan

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Golestan, Ahvaz

City

Ahvaz

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 and Technology of Ahvaz
Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Vice Chancellor for Research and Technology of
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Parisa Kazemi

Position

General physician

Other areas of specialty/work

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Vice Chancellor for Research and Technology of
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Assistant professor

Other areas of specialty/work

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Person responsible for updating data

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Parisa Kazemi

Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty