

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Dec 2019

Comparison of the effects of preemptive acetaminophen, ibuprofen, and meloxicam on pain after separator placement: a randomized clinical trial

Protocol summary

Summary

In this double blind randomized clinical trial study effect of meloxicam, ibuprofen and acetaminophen on post separator pain will be evaluated and compared. 321 patients who need fixed orthodontic therapy and are older than 15 years old will be selected. All participants must have the following criteria: not currently using antibiotics, analgesics; anti - inflammatory, anti-coagulative, diuretics, oral anti diabetics, lithium, cyclosporine and methotrexate; no need for antibiotic prophylaxis; no chronic systemic disease or clotting disorders; not reporting contraindication for NSAIDs; not pregnant or nursing. Patient who use any other analgesic during the period of study will be excluded. The patients will be divided to three groups: group A (650 mg acetaminophen), group B (400 mg ibuprofen) and group C (7.5 mg meloxicam). All patients will be given only one tablet, 1 hour before separator placement. A visual analogue scale (VAS) will be used to determine the degree of the pain and discomfort at the following intervals: Immediately after separator placement, 2 hours post treatment, 6 hours post treatment, 24 hours post treatment, and 48 hours after separator placement. Patients will be instructed to mark the degree of the pain with a short vertical line on the VAS during three oral situations including rest, fitting posterior teeth, and chewing, and return the questionnaire in the next visit (a week later).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041821828N1**
 Registration date: **2015-06-05, 1394/03/15**
 Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-05, 1394/03/15

Registrant information

Name

Neda Babanouri

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 713230541019

Email address

stud3961854483@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2015-02-11, 1393/11/22

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of preemptive acetaminophen, ibuprofen, and meloxicam on pain after separator placement: a randomized clinical trial

Public title

Effect of meloxicam on orthodontic pain

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: not currently using antibiotics; analgesics, anti - inflammatory, anti-coagulative, diuretics, oral anti diabetics, lithium, cyclosporine and methotrexate; no need for antibiotic prophylaxis; no chronic systemic disease or clotting disorders; not reporting contraindication for NSAIDs; not pregnant or nursing exclusion criteria: use any analgesic during the study time

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

None

Sample size

Target sample size: **321**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Science

Street address

central building of Shiraz University of Medical Science, Zand avenue, Shiraz, Iran

City

Shiraz

Postal code

71348-14336

Approval date

2010-11-13, 1389/08/22

Ethics committee reference number

CT-P-8928-2168

Health conditions studied

1

Description of health condition studied

post separator placement pain

ICD-10 code

R52.0

ICD-10 code description

acute pain

Primary outcomes

1

Description

post separator pain

Timepoint

immediately, 2 hour, 6 hour, 24 hour and 48 hour after

separator placement

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

ibuprofen 400 mg orally one hour before separator placement

Category

Treatment - Drugs

2

Description

acetaminophen 650 mg orally one hour before separator placement

Category

Treatment - Drugs

3

Description

meloxicam 7.5 mg orally one hour before separator placement

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontic Clinic of Dental School at Shiraz University of Medical Sciences, Iran

Full name of responsible person

Street address

Dental school, Ghasr-al-dasht avenue, Shiraz, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Dr. Basir Hashemi ,Vice President of research

Street address

central building of Shiraz university of Medical Science, Shiraz, Iran

City

Shiraz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Shiraz University of Medical Science
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
 Shiraz University of Medical Science
Full name of responsible person
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Person responsible for updating data

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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