

# 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**  
 Neda Babanouri  
**Position**  
 post graduated student of orthodontics  
**Other areas of specialty/work**  
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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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