

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparative effects of ibuprofen administration before surgery on reduction of pain after removal of impacted third molar between women and men

Protocol summary

Summary

The aim of study is to compare the effect of preemptive analgesic use for reduction of pain after third molar removal between men and women. Healthy patients having impacted third molar that need partial removal of bone for extraction with ages of 18 to 40 yrs old (30 men and 30 women) will be included in the study after signing the consent form. Patients with a history of peptic ulcer or systemic disease, hypersensitivity to NSAIDs or used pain medication within 8 hrs of surgery and pregnant women will be excluded from the study. Ibuprofen 400mg will be given to each participant, one hour before surgery. Patients are asked to record their pain intensity on a visual analogue scale (VAS) during 24 hrs after surgery. 20 tablets of ibuprofen 400 mg will be given to each patient to consume as needed for pain relief. Patients are asked to report total number of tablets consumed within 24 hrs after the surgery and also to report the time of first tablet taken after surgery. Dental anxiety of patients will be assessed by Corah's anxiety scale before surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204279566N1**
Registration date: **2014-04-17, 1393/01/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-17, 1393/01/28

Registrant information

Name

Masoumeh Emamghoreishi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 7591

Email address

emamm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-08-01, 1392/05/10

Expected recruitment end date

2014-07-29, 1393/05/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of ibuprofen administration before surgery on reduction of pain after removal of impacted third molar between women and men

Public title

Evaluating the effects of ibuprofen administration before surgery on reduction of pain after removal of wisdom teeth in women and men

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria 1. have impacted third molar in lower jaw (one or two side) 2. Having teeth needed partial

removal of bone for extraction 3. Lack of history of GI disease and peptic ulcer 4. Lack of systemic diseases such as diabetes, chronic renal failure, chronic hepatic impairment, ... 5. Lack of hypersensitivity to aspirin or related compounds 6. Lack of use of drugs that interfere with analgesic effects of NSAIDs. Exclusion criteria: 1- Active infection immediately before or after surgery. 2- Use of other analgesics within 8 hours of surgery. 3- History of gastric ulcers or erosion. 4-history of anti coagulation therapy 5- History of asthma, nasal polyps, and allergic disorders associated with aspirin and other NSAID. 6- Uncontrolled systemic diseases 7- Female patients who were pregnant or who were not using an accepted form of birth control.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Street, Shiraz university of medical sciences

City

Shiraz

Postal code**Approval date**

2011-08-01, 1390/05/10

Ethics committee reference number

CT-90-3249

Health conditions studied**1****Description of health condition studied**

Third molar extraction

ICD-10 code

k01.1

ICD-10 code description

An impacted tooth is a tooth that has failed to erupt because of obstruction by another tooth

Primary outcomes**1****Description**

Pain intensity

Timepoint

Within 24 hrs of surgery with 2 hrs time intervals

Method of measurement

VAS

Secondary outcomes**1****Description**

Total analgesic consumption and time to first analgesic use

Timepoint

Within 24 hrs after the surgery

Method of measurement

Self report

Intervention groups**1****Description**

Administration of 400 mg ibuprofen tablet before usual third molar extraction by a surgeon

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of dentistry, department of orofacial surgery

Full name of responsible person**Street address****City**

Shiraz

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vice Chancellor of Research- Dr. Syed Basir Hashemi

Street address

#7 floor, Central building, Shiraz university of Medical Sciences, Zand street

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 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

Shiraz University of Medical Sciences- Medical School

Full name of responsible person

Dr. Masoumeh Emamghoreishi

Position

Associate professor/PhD

Other areas of specialty/work

Street address

Department of pharmacology- School of Medicine- Zand Street-

City

Shiraz

Postal code

7134853185

Phone

+98 71 1230 7591

Fax

Email

emamm@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Emamghoreishi

Position

Associate professor/PhD

Other areas of specialty/work

Street address

Department of pharmacology- School of Medicine- Zand street-

City

shiraz

Postal code

7134853185

Phone

+98 71 1230 7591

Fax

Email

emamm@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Emamghoreishi

Position

PhD in Pharmacology

Other areas of specialty/work

Street address

Department of Pharmacology, School of Medicine, Zand Street

City

Shiraz

Postal code

7134853185

Phone

+98 71 1230 7591

Fax

emamm@sums.ac.ir

Email

Web page address

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