

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Survey of effect of preemptive combination of acetaminophen, ibuprofen and caffeine (novafen) on pain relief and analgesic use after surgery of impacted mandible third molars

Protocol summary

Summary

Study objective: To assess the effects of pretreatment with combination of acetaminophen, ibuprofen, caffeine, on the pain after surgery of impacted mandible third molars. Type of study: randomized, double-blind, placebo controlled. Study population: 108 patients having met the inclusion criteria and exclusion criteria, age range 18-65 years, regardless of gender, that were referred to Dental School, Hamadan University of Medical Sciences for Surgery of impacted mandible third molars in 2012, were presented randomize in two groups of 54 subjects (control and intervention). Inclusion criteria: patients with impacted mandible third molar need surgery without pain, have a healthy body and able to take medications orally. Exclusion criteria: presence of pain, the use of any pain killer before surgery, having certain medical conditions such as Contraindications for anesthesia, drug allergy, heart disease, thyroid toxicity, immune problems, hypertension, diabetes mellitus and renal and hepatic disease. Interventions: for the control group placebo and for the intervention group combination of acetaminophen, Ibuprofen, caffeine is used. Interventions time: the first doses (placebo and nova fen) is given 2 hours before the painful stimulation. The patient is taught only in the post-operative medication (Gelofen) that is moderate or severe pain to reach. The amount of analgesic drugs (Gelofen) and the amount of pain, using Visual Analog Scale (VAS), will be assessed up to 8 hours after surgery once every 2 hours (2-4-6-8 h).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201078639N1**
Registration date: **2014-01-10, 1392/10/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-10, 1392/10/20

Registrant information

Name

Hosein Kimiaei Asadi

Name of organization / entity

Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of effect of preemptive combination of acetaminophen, ibuprofen and caffeine (novafen) on pain relief and analgesic use after surgery of impacted

mandible third molars

Public title

Effect of preemptive novafen on pain relief after impacted tooth surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with impacted mandible third molar need surgery without pain, have a healthy body and able to take medications orally. Exclusion criteria: presence of pain, the use of any pain killer before surgery, having certain medical conditions such as Contraindications for anesthesia, drug allergy, heart disease, thyroid toxicity, immune problems, hypertension, diabetes mellitus and renal and hepatic disease.

Age

To **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

This is a randomized, double-blind study. Randomization and design of the study are as follows: 108 bags were made of dark colors on them were written the numbers 1 to 108. The bags were divided randomly into two groups of 54. Each card was placed inside a bag on which the letter A (the group treated with the combination of 600 mg of ibuprofen 400 mg of acetaminophen and 15 mg caffeine) or the letter B (placebo group) was written. The letter A or B, which was placed inside the bags were determined using random numbers table. So 54 bags containing the letter A and The 54 bags containing the letters B were prepared and were given to first collaborator that he was not aware about grouping. First Patient opened the first bag and the letter inside the bag (1) determined the patient group (A or B). Other patients in the two groups were subjected to the same procedure. Since drug and placebo had exactly similar package; the collaborator who delivered the required package to patients did know the sort of drug. Packaging and coding of administered medicine was carried out by research co-coordinator and none of patients or other researchers were aware of this grouping. Therefore the study was double blind. After taking the drug and follow up period, physical examination and patient`s information were

collected by a collaborator that was unaware of the grouping and sort of intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh street, Hamadan, IRAN

City

Hamadan

Postal code

Approval date

2012-06-27, 1391/04/07

Ethics committee reference number

1278/9/35/16/د/ب

Health conditions studied

1

Description of health condition studied

impacted teeth

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

Analgesics

Timepoint

2,4,6 and 8 h after the operation.

Method of measurement

Based on the number

2

Description

PAIN

Timepoint

2,4,6 and 8 h after the operation.

Method of measurement

using a 10-point visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

2 Hours Before Surgery, intervention group were given a single dose of the oral combination drug brand Novafen that it is made in Alvahi factory (Acetaminophen (600 mg) + Ibuprofen (400 mg) + caffeine (15 mg))

Category

Treatment - Drugs

2

Description

2 Hours Before Surgery, control group were given a single dose of the oral Vitamin C (250 mg) that it is made in Darou Pakhsh factory.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan University of Medical Sciences

Full name of responsible person

Hosein Kimiaei Asadi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street, Hamadan, IRAN

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Hamadan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Vice Chancellor for research, Hamadan University of Medical sciences, Shahid Fahmideh Street, Hamadan, IRAN

City

Hamadan

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, Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Hosein Kimiaei Asadi

Position

Anesthesiologist

Other areas of specialty/work

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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