# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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
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Hamadan University of Medical Scienses
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Iran (Islamic Republic of)
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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**
2,4,6and 8 h after the operation.
**Method of measurement**
Based on the number

### 2

**Description**
PAIN
**Timepoint**
2,4,6and 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 Alhavi 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
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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
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**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**
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Hamadan University of Medical Sciences
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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*