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

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Hosein Kimiaei Asadi
Name of organization / entity
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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
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Hosein Kimiaei Asadi
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Hamadan University of Medical Sciences, Shahid Fahmideh Street,Hamadan,IRAN
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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
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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

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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