Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of Novafen prescription versus combination of Acetaminophen codeine and Ibuprofen on pain after surgical extraction of wisdom teeth

Protocol summary

Summary

objective: to determine a standard protocol for pain control after wisdom teeth surgeries. Inclusion criteria:1. age between 18-30 2.physical status ASA 1,2 Exclusion criteria:allergy and systemic diseases the randomized double blind controled clinical trial on 80 patients who reffered to kerman dental school,oral and maxillofacial surger deparment is performed in 2014 . 2 groups of 40 patients selected randomy from men and women who candidate for third molar surgery, acoording to date of admitting.2 groups were similar in age ,sex and difficulty of surgery.after filling the consent form and performing surgery ,one group recieved 20 tablets of novafen and placebo and another group recieved 20 tablets of acetaminophen codein and ibubrofen 200.but the patient and surgeon dont know the drug.patients recieve codes,then they complete the pain 3,6,12,24,48 hours after surgery according to VAS (visual analog scale) scales.then the data would be statically analyzed.patients can quit this study if they would not want want to follow the protocols sample size: with a=0.05 and B=0.1,the sample size was 40 for each group interventions:analgesis drugs novafen and acetaninophen cod and ibubrofen outcome:analgesia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091919228N1**
Registration date: **2014-12-19, 1393/09/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-19, 1393/09/28

Registrant information

Name

Sahand Samieirad

Name of organization / entity

Oral & maxillofacial surgery ward,oral & dental research center,kerman dental university, Iran

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Recruitment status

Recruitment complete

Funding source

Kerman Dental and Oral disease research center, Kerman University of Medical Sciences.

Expected recruitment start date

2014-12-11, 1393/09/20

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Novafen prescription versus combination of Acetaminophen codeine and Ibuprofen on pain after surgical extraction of wisdom teeth

Public title

Evaluation the prescription effect of Novafen versus combination of Acetaminophen codeine and Ibuprofen on pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1. age between 18-30 2.physical status ASA 1,2 3.without analgesic use history 4.without oral and maxillofacial surgery history 5.without oral and maxillofacial trauma history 6.having one mesioangular lower third molar with pell & gregory class I ,A 7.without previous wisdom teeth surgery 8.without using alcohol and narcotics 9.without asthma history 10.without gastic ulcer and GI bleeding Exclusion criteria: 1.oral and maxillofacial surgery and admission history 2.having any chronic systemic or psychosomatic disease 3.having history or risk of infective endocarditis 4.having bleeding disease or using anticoagulant drugs like asorin 5.using alcohol and narcotics 6.acute local infection 7.allergy to codein or cafeine 8.pregnancy or lactating period

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

dental and oral disease center,kerman university of medical sciences

Street address

kerman,jomhoori blv,shafa st

City

kerman

Postal code

76175

Approval date

2014-12-02, 1393/09/11

Ethics committee reference number

۲۸/ ع

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

analgesic type

Timepoint

each 8 hours after surgery

Method of measurement

mg dose

Secondary outcomes

1

Description

pain

Timepoint

3,6,12,24,48 hours after surgery

Method of measurement

VAS scal

Intervention groups

1

Description

tablet Novafen 400 mg ,each 8 hours after surgery,for 1 week (20 numbers)

Category

Treatment - Drugs

2

Description

tab acetaminophen codein 320 mg and ibubrofen 200 mg each 8 hours after surgery,for one week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

kerman dental school,oral and maxillofacial surgery ward

Full name of responsible person

dr sahand samieirad
Street address
kerman dental university, shafa st,Kerman,Iran
City
kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research center,kerman university of medical sciences
Full name of responsible person
dr gholamreza sepehri
Street address
kerman,tahmaseb abad ave, jahad st,research center
City
kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research center,kerman 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
kerman dental school,oral and maxillofacial surgery department
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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