Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Comparison the effects of fentanyl, sufentanil and alfentanil as premedication on postoperative nausea and vomiting in diagnostic gynecologic laparascopy in hundred eighty patients (ASA I and II), aged 18-35 year

Protocol summary

Summary

Introduction: Reduction of post operative nausea and vomiting accelerates discharge of patients and reduces healthcare costs, hospital re–admission and duration of hospitalization, and increases satisfaction of patients. Methods: This study was an interventional experiment performed on 180 patients undergoing GLS. Patients were selected from those who referred to afzalipoor hospital of Kerman for diagnostic GLS and were aged 18-35 with ASA I or II. This study was approved by the hospital ethics research committee [Code: EC/KNRC/88-169] and registered with the European Clinical Trials Database. Exclusion criteria included: diabetes, addiction to drugs, history of nausea or vomiting and or using drugs with known anti-emetic properties (like metformin, clomifen, medroxy progestron, bromocriptin) 24 hours before the surgery, smoking, motion disease history, previous experience of PONV, surgical duration more than 45 minutes, usage of opioids after surgery in recovery period and weight more than 70kg. They were randomly allocated to three groups: alfentanil, sufentanil and fentanyl. After entrance of the patient to the OR, alfentanil 2cc (1000µg); fentanil 2cc (100µg); sufentanil 2cc (10µg) was administered to the three group of patients two minutes before I.V. induction of anesthesia to the patient. After surgery and extubation and entrance into recovery ward, incidence of nausea or vomiting was recorded from the entrance to the ward until 24 hours after surgery in the check list by a resident of anesthesiology who was blinded to the drug administered to the patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810293104N1**
Registration date: **2012-08-24, 1391/06/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-08-24, 1391/06/03

Registrant information

Name
Mohammad Shabani
Name of organization / entity
Kerman Neuroscience Research Center
Country
Iran (Islamic Republic of)
Phone
+98 34 1226 4196
Email address
shabani@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of fentanyl, sufentanil and alfentanil as premedication on postoperative nausea and vomiting in diagnostic gynecologic laparascopy in hundred eighty patients (ASA I and II), aged 18-35 year

Public title
Comparison the effects of fentanyl, sufentanil and alfentanil as premedication on postoperative nausea and vomiting in diagnostic gynecologic laparascopy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Patients were selected from those who referred to afzalipoor hospital of Kerman for diagnostic GLS and were aged 18-35 with ASA I or II. Exclusion criteria: diabetes mellitus; addiction to drugs; history of nausea or vomiting and or using drugs with known anti-emetic properties (like metformin, clomifen, medroxy progestron, bromocriptin) 24 hours before the surgery; smoking; motion disease history; previous experience of PONV; surgical duration more than 45 minutes; usage of opioids after surgery in recovery period and weight more than 70kg. After signing informed consent by all the patients, 180 subjects were enrolled in the study.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kerman University of Medical Sciences Ethics Committee
Street address
Somayeh crossroad- Kerman Neuroscience Research Center
City
Kerman
Postal code
Approval date
2009-04-21, 1388/02/01
Ethics committee reference number
172/89/ک

Health conditions studied

1

Description of health condition studied
gynecologic
ICD-10 code
N80-N98
ICD-10 code description
N80-N98

Primary outcomes

1

Description
Vomitting
Timepoint
0-24, 0-2, 2-24(0-24 hours after surgury)
Method of measurement
Observation

2

Description
Nausea
Timepoint
0-24, 0-2, 2-24(0-24 hours after surgury)
Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
Midazolam 1mg and alfentanil 2cc (1000µg). Induction of every three group was performed using thiopental (5mg/kg) and succynyl choline (1.5mg/kg), anesthesia was maintained using isoflurane 1.2% gas and a mixture of N2O-O2 with 50/50 ratio. Due to the short duration of surgery, there was no need to repeat administration of opioid drug and in the case of surgery lasting more than 45 minutes and repetition of opioid administration, patient was excluded from the study.
Category
Treatment - Drugs

2

Description

Midazolam 1mg and fentanil 2cc (100µg); was administered to the patients two minutes before I.V. induction of anesthesia to the patient (each 1cc of the three drugs has equal power). Induction of every three group was performed using thiopental (5mg/kg) and succynyl choline (1.5mg/kg), anesthesia was maintained using isoflurane 1.2% gas and a mixture of N2O-O2 with 50/50 ratio. Due to the short duration of surgery, there was no need to repeat administration of opioid drug and in the case of surgery lasting more than 45 minutes and repetition of opioid administration, patient was excluded from the study.

Category

Treatment - Drugs

3

Description

Midazolam 1mg and sufentanil 2cc (10µg) was administered to the patients two minutes before I.V. induction of anesthesia to the patient (each 1cc of the three drugs has equal power). Induction of every three group was performed using thiopental (5mg/kg) and succynyl choline (1.5mg/kg), anesthesia was maintained using isoflurane 1.2% gas and a mixture of N2O-O2 with 50/50 ratio. Due to the short duration of surgery, there was no need to repeat administration of opioid drug and in the case of surgery lasting more than 45 minutes and repetition of opioid administration, patient was excluded from the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Street address

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy research and tecnology in kerman medical university

Full name of responsible person

dr taravati

Street address

kerman medical university

City

kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy research and tecnology in kerman medical university

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 Neuroscience Research Center

Full name of responsible person

Mohammad Shabani

Position

PhD

Other areas of specialty/work

Street address

Kerman

City

Kerman

Postal code

Phone

+98 34 1226 4198

Fax

Email

shabanimoh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Neuroscience Research Center- kerman medical university

Full name of responsible person

Mohammad Shabani

Position

PhD

Other areas of specialty/work

Street address

Neuroscience Research Center- kerman medical universi

City

Kerman

Postal code

Phone

+98 34 1226 4196

Fax

Email

shabani@kmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
kerman medical university

Full name of responsible person
mohammad shabani

Position
PhD

Other areas of specialty/work

Street address
kerman neuroscience research center

City
kerman

Postal code

Phone
+34 12264196

Fax

Email
shabanimoh@yahoo.com

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