

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Postoperative Shivering after Remifentanil-Propofol versus fentanyl-propofol Intravenous Anesthesia in patients undergoing ambulatory Gynecologic Procedures

Protocol summary

Summary

Postanesthesia shivering (PAS) is a frequent side effect of general anesthesia and one of the leading causes of patients discomfort after recovery from anesthesia especially in ambulatory setting. The aim of this study was to evaluate the effects of remifentanil versus fentanyl on postoperative shivering and its relationship with intraoperative hypothermia. In this double blind randomized clinical trial, after receiving an written informed consents, 110 patients with American Society of Anesthesiology (ASA) physical status I or II, scheduled for ambulatory gynecologic procedures, will randomly assign to one of two groups of 55. Basic vital signs (arterial blood pressure, heart rate and Sao₂) and core body tympanic membrane temperature will be measured and recorded. Room temperature will be adjusted at 22-24 °C. Fluids temperature will be equal to the operating rooms temperatures. General anesthesia will induce with midazolam 0/05 mg/kg IV, propofol 2-2.5 mg/kg IV and follow by infusion of propofol 5-10µg/kg/h in both groups. In remifentanil group remifentanil 1 µg/kg IV will be administered for induction and infused in the range of 0.1-0.25 µg/kg/h for maintenance of anesthesia. In fentanyl group, fentanyl 1 µg/kg IV will be administered for induction and repeated as needed for maintenance of anesthesia. Patients' vital signs and core body temperatures will be recorded throughout surgery at certain intervals. After surgery, patients will be evaluated in recovery room for hemodynamic variables and severity of shivering(according to Wrench five-point rating score) as well as Pain, nausea-vomiting and agitation every 15 minutes until discharge from recovery. Analysis will be performed using SPSS 16.0 program.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015043011700N7**

Registration date: **2015-08-20, 1394/05/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-20, 1394/05/29

Registrant information

Name

Farnaz Moslemi Tabrizi

Name of organization / entity

Alzahra hospital, Tabriz university of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Tabriz Azad University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Postoperative Shivering after Remifentanil-Propofol versus fentanyl-propofol Intravenous Anesthesia in patients undergoing ambulatory Gynecologic Procedures

Public title

Evaluation of the effect of remifentanil on postoperative shivering after ambulatory gynecologic procedures

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: patients with American Society of Anesthesiology (ASA) physical status I or II; patients scheduled for ambulatory gynecologic procedures
 Exclusion criteria: patients with ASA class III or higher; patients with cardiopulmonary diseases; Preoperative fever; use of any anti pyretic or anti-inflammatory medication; any surgery time longer than 2 hours

AgeFrom **17 years** old to **52 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **100****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**

Tabriz Islamic Azad University ,faculty of Medicine

Street address

Faculty of Medicine,Manzarieh ave,Tabriz

City

tabriz

Postal code**Approval date**

2014-12-20, 1393/09/29

Ethics committee reference number

8705385029423

Health conditions studied**1****Description of health condition studied**

Postoperative shivering

ICD-10 code

R00-R99

ICD-10 code description

R68.0 Hypothermia, not associated with low environmental temperature ,hypothermia (due to)(of):anaesthesia (T88.5)

Primary outcomes**1****Description**

Severity of postoperative shivering

Timepoint

in recovery every 15 minutes until discharge from recovery

Method of measurement

Crossly and Mahjon five-point scoring system

Secondary outcomes**1****Description**

pain

Timepoint

in recovery room every 15 minutes until discharge from recovery

Method of measurement

visual analog score

Intervention groups**1****Description**

Interventional group: In remifentanil group, general anesthesia will induce with midazolam 0.05 mg/kg IV, propofol 2-2.5 mg/kg IV and follow by infusion of propofol 5-10µg/kg/h. Then, remifentanil 1 µg/kg IV was administered for induction and infused in the range of 0.1-0.25 µg/kg/h for maintenance of anesthesia according to the patient's heart rate and blood pressures variations. .

Category

Prevention

2**Description**

Control group: In group fentanyl (group F) general anesthesia will induce with midazolam 0.05 mg/kg IV,

propofol 2-2.5 mg/kg IV and follow by infusion of propofol 5-10µg/kg/h .Then, fentanyl 1 µg/kg IV was administered for induction and repeated as needed for maintenance of anesthesia to keep the depth of anesthesia according to the patient's heart rate and blood pressures variations.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

AlzahraTeaching Hospital ,Tabriz University of Medical Sciences

Full name of responsible person

Dr Farnaz Moslemi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Tabriz azad Islamic University ,faculty of Medicine

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**

Research Center, Tabriz University of Medical Sciences

Full name of responsible person

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Position

Associate Professor, Specialist in Anesthesiology

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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