

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 Sao<sub>2</sub>) 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1553 9161

##### Email address

moslemif@tbzmed.ac.ir

##### 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

**Age**From **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

**Street address**

Alzahra Teaching Hospital,south Artesh ave

**City**

Tabriz

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

Tabriz azad Islamic University ,faculty of Medicine

**Full name of responsible person**

dr Farnaz Moslemi

**Street address**

Tabriz, Artesh Ave, Alzahra Hospital

**City**

Tabriz

**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**

Farnaz Moslemi

**Position**

Associate Professor, Specialist in Anesthesiology

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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*