

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Evaluating the Effect of Intraoperative Dextrose Infusion for Prevention of Nausea and Vomiting after Diagnostic Gynecologic Laparoscopy

#### Protocol summary

##### Summary

Postoperative nausea and vomiting (PONV) remains one of the most common postoperative complications. The aim of the present study is to evaluate the effect of infusion iv dextrose solution beginning with the start of surgery to end of operation for prophylaxis of PONV in patients undergoing diagnostic gynecologic laparoscopy under general anesthesia. In this clinical trial 70 ASA physical status I non-diabetic patients and aged 20-70 years, scheduled for diagnostic gynecologic laparoscopy are randomly assigned to infusion of 10 mL/kg/h Ringer's solution with 0.5 g/kg dextrose in study group ( n = 35) or Ringer's solution alone in placebo group ( n = 35) during surgery. Blood glucose is determined using a glucometer in the operating room immediately before study fluid infusion and in the recovery room. PONV scores using by (0= non; 1= nausea; 2=vomiting; and 3= vomiting > 3 times) scoring in recovery room and at 3, 6, and 24 hours postoperatively, first request to antiemetic , and total dose of antiemetic medication are recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201402047013N10**

Registration date: **2014-02-10, 1392/11/21**

Registration timing: **na**

Last update:

Update count: **0**

##### Registration date

2014-02-10, 1392/11/21

##### Registrant information

##### Name

Simin Atashkhoei

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3333 3806

##### Email address

atashkhoei@tbzmed.ac.ir

##### Recruitment status

**Not enough for processing**

##### Funding source

Research Vice Chancellor, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-12-30, 1392/10/09

##### Expected recruitment end date

2013-12-29, 1392/10/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the Effect of Intraoperative Dextrose Infusion for Prevention of Nausea and Vomiting after Diagnostic Gynecologic Laparoscopy

##### Public title

Effect of Intraoperative Dextrose Infusion for Prevention of Nausea and Vomiting after Diagnostic Gynecologic Laparoscopy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Women aged 20-40 years; ASA class 1; scheduled for diagnostic gynecologic laparoscopy  
Exclusion criteria: vaginal hemorrhage; taking any medication, including corticosteroids , opioids and

antiemetics; history of systemic disease( cardiovascular, respiratory, renal ,...); history of motion sickness; history of gastrointestinal disease; pregnancy

#### **Age**

From **20 years** old to **40 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **70**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Research Vice Chancellor, Tabriz University of Medical Sciences

###### **Street address**

Research Vice Chancellor; Tabriz University; Daneshgah Street; Tabriz

###### **City**

Tabriz

###### **Postal code**

##### **Approval date**

2013-12-30, 1392/10/09

##### **Ethics committee reference number**

92164

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Postoperative nausea and vomiting

##### **ICD-10 code**

Y84

##### **ICD-10 code description**

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

### **Primary outcomes**

#### **1**

##### **Description**

Severity of postoperative nausea and vomiting

##### **Timepoint**

Recovery and at 3, 6, and 24 h postoperatively

##### **Method of measurement**

scoring by (0=non, 1=nausea, 2=vomiting, 3=vomiting >2 times)

### **Secondary outcomes**

#### **1**

##### **Description**

Total dose of antiemetic

##### **Timepoint**

recovery and during 24 hpostoperatively

##### **Method of measurement**

mg

### **Intervention groups**

#### **1**

##### **Description**

In the study group is infused 10 ml/kg/h Ringer's solution with 0.5 g/kg dextrose during surgery.

##### **Category**

Prevention

#### **2**

##### **Description**

In the placebo group (n=35) is infused of 10 ml/kg/h Ringer's solution alone in placebo during surgery.

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Al-Zahra Hospital

###### **Full name of responsible person**

Dr. Simin Atashkhoyi

###### **Street address**

Alzahra Hospital, South Artesh Ave, Tabriz

###### **City**

Tabriz

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

**Name of organization / entity**

Research Vice Chancellor, Daneshgah Street, Tabriz

**Full name of responsible person**

Dr. Rashidi

**Street address**

Research Vice Chancellor, Daneshgah Street, Tabriz

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research Vice Chancellor, Daneshgah Street, Tabriz

**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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Simin Atashkhoyi

**Position**

Anesthesiologist/ Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*