# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jun 2026

## The effect of intraperitoneal spillage of rupivacaine and ketamine in combination with lung recruitment to reduce pain after laparoscopic gynecological procedures

## Protocol summary

**Study aim**

Determining the effect of intraperitoneal injection of ropivacaine and ketamine to reduce pain after laparoscopic surgeries in women.

**Design**

prospective and randomized double-blind clinical trial. To determine the sample size with determination software the number of 50 studied samples was obtained, and the patients were selected by easy sampling method. Consecutively, based on the order of reference and using Rand List online randomization software, they will be randomly divided into two equal groups of 25 people and will be included in the study.

**Settings and conduct**

Patients will be blinded to the type of injected drug.the medicine will be drawn in a syringe by the scrub nurse who is not aware of the study and will be sprayed by the surgeon. This amount will not be suctioned and will remain inside the stomach. Data collection will be done by an anesthetist who is unaware of the type of injected drug

**Participants/Inclusion and exclusion criteria**

Female with physical condition II or I ASA class candidate for laparoscopic surgery in the age range of 18-60 years in Al-Zahra Hospital, Tabriz. Patient consent to enter the study

**Intervention groups**

Candidates for laparoscopic surgery at Al-Zahra Hospital will be randomly divided into two groups. After surgery, in the study group, ropivacaine 0.2% and ketamine 0.5 milligrams per kilogram in a total volume of 50 cc will be poured by the surgeon into the intraperitoneal space and the surgical site, and in the control group, 50 cc of normal saline will be used.

**Main outcome variables**

Reducing the severity of abdominal and shoulder pain after surgery in two study groups; Comparison of hemodynamic changes during and after surgery in two study groups

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20221117056529N1**
Registration date: **2023-03-10, 1401/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-10, 1401/12/19**
Update count: **0**

**Registration date**

2023-03-10, 1401/12/19

**Registrant information**

**Name**

Samin Ehsaninezhad

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 3725 5435

**Email address**

saminehsani100@yahoo.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-02-09, 1401/11/20

**Expected recruitment end date**

2023-08-11, 1402/05/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of intraperitoneal spillage of rupivacaine and ketamine in combination with lung recruitment to reduce pain after laparoscopic gynecological procedures

**Public title**

reduce pain after laparoscopic gynecological procedures

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

II or I ASA class , candidates for laparoscopic surgery for women in the age range of 18-60 years in Al-Zahra Hospital, Tabriz Patient consent to enter the study

**Exclusion criteria:**

The existence of any contraindications to the use of ropivacaine and other local anesthetics The presence of any contraindications for ketamine use: history of seizures, psychological disorders, hypertension, high intracerebral pressure, etc. Hypersensitivity to ropivacaine or other local anesthetics and ketamine Concomitant systemic diseases such as any history of cardiovascular, pulmonary, liver, kidney, etc. Presence of chronic pain in the patient Addiction to the use of painkillers and drugs Patient dissatisfaction

**Age**

From **18 years** old to **60 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using random numbers table, they will be randomly divided into two groups of 25 people in the study and 25 people in the control group. In such a way that in the event of odd, they would be in rupivacaine and ketamine and in the event of even, they would be in Sodium Chloride 0.9% group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The administration of anesthesia and fluids (volume and type of serum) during anesthesia is performed by an anesthesiologist and anesthesia technician, and all data will be collected and recorded in the checklist by an anesthesiologist who is unaware of the division of the groups. patient are also unaware of the division of the groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tabriz Medical Sciences

**Street address**

Talash dormitory ,Pish ghadam,kamar bandiye miyani

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5163996937

**Approval date**

2022-07-12, 1401/04/21

**Ethics committee reference number**

IR.TBZMED.REC.1401.320

## Health conditions studied

### 1

**Description of health condition studied**

The effects of the combination of ropivacaine and ketamine, pain reduction, laparoscopic surgeries for women

**ICD-10 code**

T88.9

**ICD-10 code description**

Complication of surgical and medical care, unspecified

## Primary outcomes

### 1

**Description**

The percentage of people in whom abdominal and shoulder pain has decreased after laparoscopic surgeries

**Timepoint**

Upon entering the operating room, standard monitoring including NIBP, HR, RR, ECG, SPO2, and ETCo2 is done and will continue. The severity of shoulder and abdominal pain is recorded every 15 minutes until the patient's complete recovery and delivery to the ward.

**Method of measurement**

The severity of shoulder and abdominal pain, based on VAS score and degree of sedation according to Ramsay sedation score, is recorded every 15 minutes until the patient's complete recovery and delivery to the ward.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: 50 women who have undergone laparoscopic surgery will be injected with ropivacaine 0.2% and ketamine 0.5 mg/kg in a total volume of 50 cc by the surgeon into the intraperitoneal space and the surgical site. In the control group, 50 cc of 0.09% normal saline serum will be used. Before the removal of trocars in both groups, lung recruitment maneuver will be performed. In the PACU, the patient will be monitored and treated if there is a specific complication. The severity of shoulder and abdominal pain, the degree of sedation will be recorded every 15 minutes until delivery to the ward, and in case of VAS scores higher than 3, treatment will be given, and the dose of supplementary drugs will also be recorded.

**Category**
Treatment - Drugs

### 2

**Description**
Control group: After surgery, 50 cc of normal saline will be used in the control group.

**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
AL zahra hospital

**Full name of responsible person**
Samin Ehsaninezhad

**Street address**
AL zahra hospital,Bagh shomal square,Artesh street

**City**
tabriz

**Province**
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**Postal code**
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**Phone**
+98 41 3553 9160

**Email**
saminehsani100@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
Parviz Shahabi

**Street address**
Next to the Emamreza hospital ,Golgasht,Tabriz

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tabriz

**Province**
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**Phone**
+98 41 3337 6923

**Email**
reyhane.abri@gmail.com

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Tabriz University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
Reyhane Abri

**Position**
Associate professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

**Street address**
AL zahra hospital,Bagh shomal square,Artesh street

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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)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
A part of the data, such as information related to the main outcome or the like, can be shared.

**When the data will become available and for how long**
Access starts from 1401

**To whom data/document is available**
It will be available for researchers working in academic and scientific institutions and even people working in industry.

**Under which criteria data/document could be used**
Data must be protected

**From where data/document is obtainable**
Samin Ehsaninezhad 09364702225fu

**What processes are involved for a request to access data/document**
Immediately after calling

**Comments**