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

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tabriz

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East Azarbaijan

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+98 41 3553 9160

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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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+98 41 3337 6923

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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

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Position
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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