

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study between enhanced and conventional recovery on postoperative outcomes in women candidates for laparoscopic surgery.

#### Protocol summary

##### Study aim

Comparison of two enhanced and conventional recovery protocols on short- and mid-term outcomes of women undergoing laparoscopic surgery.

##### Design

This is a double blind randomized clinical trial study. Patients will be randomly divided using a random number table into two groups(intervention and control).

##### Settings and conduct

This is a double blind randomized clinical trial study. Patients referred to Hazrat Rasool Akram Hospital in 2019-2020 according to inclusion criteria will be enrolled to the study.

##### Participants/Inclusion and exclusion criteria

In this study patients who are candidates laparoscopic for gynecological surgery which not being anemia, not being infected, do not suffer from underlying disease, and BMI<25.5 will be enrolled to the stud. Exclusion criteria will be included: conversion from laparoscopic surgery to laparotomy, more interventions (blood transfusions,.....), occurrence of unpredictable complications during surgery, the unwillingness of women to continue the study.

##### Intervention groups

The intervention group will be patients who were laparoscopic candidates for gynecological surgery and will receive an enhanced recovery. The intervention group will be patients who were laparoscopic candidates for gynecological surgery and will receive a conventional recovery.

##### Main outcome variables

The primary outcome in this study would be pain score, need for analgesia, fever, nausea and vomiting, diarrhea, postoperative infection, length of hospital stay, hemoglobin changes, bleeding rate, resumption of bowel activity.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191123045476N1**

Registration date: **2020-05-21, 1399/03/01**

Registration timing: **retrospective**

Last update: **2020-05-21, 1399/03/01**

Update count: **0**

##### Registration date

2020-05-21, 1399/03/01

##### Registrant information

##### Name

Samaneh Rokhgireh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6650 9283

##### Email address

rokhgireh.s@iums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-10-23, 1398/08/01

##### Expected recruitment end date

2020-05-21, 1399/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study between enhanced and conventional recovery on postoperative outcomes in women candidates for laparoscopic surgery.

#### Public title

Comparative study between enhanced and conventional recovery on postoperative outcomes in women candidates for laparoscopic surgery.

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Not being anemia Not being infected Do not suffer from underlying disease (heart, lung, gastrointestinal, thyroid, nervous, mental, etc.). BMI<25.5

##### Exclusion criteria:

Conversion from laparoscopic surgery to laparotomy The unwillingness of women to continue the study. More interventions (blood transfusions,.....) Occurrence of unpredictable complications during surgery

#### Age

No age limit

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

- Investigator
- Data analyser

#### Sample size

Target sample size: **160**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this study, the patients will be randomly assigned to one of two groups by a computer-generated random table block of size 4.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study, the principal investigator and data analyser will be kept blind to the assigning groups of the study.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

###### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1986663311

##### Approval date

2019-10-13, 1398/07/21

##### Ethics committee reference number

IR.IUMS.REC.1398.724

### Health conditions studied

#### 1

##### Description of health condition studied

Laparoscopic gynecological surgery

##### ICD-10 code

Z53.31

##### ICD-10 code description

Laparoscopic surgical procedure converted to open procedure

### Primary outcomes

#### 1

##### Description

Pain score

##### Timepoint

After surgery

##### Method of measurement

Questionnaire and medical records

#### 2

##### Description

Need for analgesia

##### Timepoint

After surgery

##### Method of measurement

Questionnaire and medical records

#### 3

##### Description

Fever

##### Timepoint

After surgery

##### Method of measurement

Questionnaire and medical records

#### 4

##### Description

nausea and vomiting

##### Timepoint

After surgery

##### Method of measurement

Questionnaire and medical records

## 5

### **Description**

Diarrhea

### **Timepoint**

After surgery

### **Method of measurement**

Questionnaire and medical records

## 6

### **Description**

Postoperative infection,

### **Timepoint**

After surgery

### **Method of measurement**

Questionnaire and medical records

## 7

### **Description**

Length of hospital stay

### **Timepoint**

After surgery

### **Method of measurement**

Questionnaire and medical records

## 8

### **Description**

Hemoglobin changes

### **Timepoint**

After surgery

### **Method of measurement**

Questionnaire and medical records

## 9

### **Description**

Bleeding volume

### **Timepoint**

After surgery

### **Method of measurement**

Questionnaire and medical records

## 10

### **Description**

Resumption of bowel activity

### **Timepoint**

After surgery

### **Method of measurement**

Questionnaire and medical records

## **Secondary outcomes**

### 1

#### **Description**

Postoperative infection

#### **Timepoint**

2 weeks after surgery

#### **Method of measurement**

Questionnaire

### 2

#### **Description**

Return to normal activity

#### **Timepoint**

2 weeks after surgery

#### **Method of measurement**

Questionnaire

### 3

#### **Description**

Return to work

#### **Timepoint**

2 weeks after surgery

#### **Method of measurement**

Questionnaire

### 4

#### **Description**

Hospital readmission.

#### **Timepoint**

2 weeks after surgery

#### **Method of measurement**

Questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group will be 80 patients who were candidates laparoscopic for gynecological surgery. Perioperatively, this group will be managed according to Enhanced Recovery After Surgery (ERAS) protocols. The basic principles of ERAS include attention to the following: preoperative counseling and nutritional strategies, including avoidance of prolonged perioperative fasting, perioperative considerations, including a focus on regional anesthetic and nonopioid analgesic approaches, fluid balance, and maintenance of normothermia, and promotion of postoperative recovery strategies, including early mobilization and appropriate thromboprophylaxis.

#### **Category**

Treatment - Surgery

### 2

#### **Description**

Control group will be 80 patients who were candidates laparoscopic for gynecological surgery. Perioperatively, this group will be managed according to conventional hospital management protocols.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Rasoul-e-Akram Hospital

**Full name of responsible person**

Samaneh Rokhgireh

**Street address**

Rasoul-e-Akram Hospital, Mazar-i-Mansouri St.,  
Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 9283

**Email**

s.rokhgireh@gmail.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Abas Motavalian

**Street address**

Hemat Highway next to Milad Tower, Iran University  
of Medical Sciences

**City**

Tehran

**Province**

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**Postal code**

1449614535

**Phone**

+98 21 6650 9283

**Email**

PR@iums.ac.ir

**Grant name****Grant code / Reference number**

13670

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Iran University of Medical Sciences

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Rokhgireh

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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### Person responsible for updating data

#### Contact

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available