Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)

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+98 21 6650 9283

Email address

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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 nonopiod analgesic approaches, fluid balance, and maintenance of norothermia, and promotion of postoperative recovery strategies, including early mobilization and appropriate thromboprophylaxia.
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

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1445613131

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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

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1449614535

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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

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