Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effect of early mobilization protocol on patients’ pain severity after laparoscopic surgery

Protocol summary

Study aim
Effect of early mobilization protocol on patients’ pain severity after laparoscopic surgery

Design
A randomized clinical trial with intervention and control groups. According to the same study, considering the difference in mean of pain (d = 0.75) and standard deviation of pain in control group (1.63) and with 95% confidence level and power of 80% the size was 37 in each group using formula. Considering 10% attrition, 40 patients will be assigned in each group. Patients will be assigned to two groups using randomized block design (block size of 4).

Settings and conduct
Study will be conducted on the candidates of laparoscopic surgery in Shahid Beheshti hospital of Kashan. Patient and his companion will be trained on mobilization (practical with photos and videos) preoperative. 3 hours after returning to the ward,with complete alertness, the instructions will repeated. The vital signs and pain will be measured. With normal vital signs, pain score below 5, no nausea,vomiting and dizziness and no medical prohibition, intervention will be started. In the control group, the mobilization will be started the day after surgery based on the routine.It is not possible to blind in this study.

Participants/Inclusion and exclusion criteria
Inclusion: no Alzheimer's, dementia, orthopedic problems and amputation.laparoscopic surgery, normal blood pressure and heart rate, no bleeding from surgery site, Willingness,physician's order for mobilization. Exclusion: refuse to continue, occurrence of surgical complications(bleeding, impaired consciousness, impaired hemodynamic), physician's recommendation not to mobilize.

Intervention groups
Three hours after returning to the ward, with complete alertness, two times mobilization intervention will be conducted on patient. The mobilization will be started in control group the day after surgery based on the routine.

Main outcome variables
Post-surgical pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100124003146N7**
Registration date: **2019-09-04, 1398/06/13**
Registration timing: **prospective**

Last update: **2019-09-04, 1398/06/13**
Update count: **0**

Registration date
2019-09-04, 1398/06/13

Registrant information

Name
Ismail Azizi-Fini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5554 0021

Email address
azizi-es@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-21, 1398/06/30

Expected recruitment end date
2019-11-21, 1398/08/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of early mobilization protocol on patients’ pain severity after laparoscopic surgery

Public title

The effect of early mobilization protocol on patients’ pain severity after laparoscopic surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Not having any physical problems preventing mobilization like Alzheimer's, Dementia, Orthopedic problems, Amputation Undergoing a diagnostic and therapeutic laparoscopic procedure Having normal blood pressure, heart rate within normal range at the start of mobilization Not having bleeding in surgery site Willingness to participate in research and collaborate with researcher Having a physician's written order for mobilization

Exclusion criteria:

Refuse to continue cooperation Occurrence of surgical complications that prevent continuing the mobilization (such as bleeding, impaired consciousness, impaired hemodynamics) Physician's recommendation not to mobilize after surgery

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who met the inclusion criteria will be randomly divided into intervention and control groups by block randomization (Blocks with size 4).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ravand Ave., Parastar Blvd.

City

Kashan

Province

Isfehan

Postal code

8715981151

Approval date

2019-07-23, 1398/05/01

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1398.023

Health conditions studied

1

Description of health condition studied

post-laparoscopic surgery pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

The severity of pain after laparoscopic surgery

Timepoint

15 minutes before and 30 minutes after the first stage of intervention, 15 minutes before and 30 minutes after the second stage of intervention

Method of measurement

Pain measurement ruler which is numbered 0-10.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Three hours after the patient returns to the ward and after complete alertness, the patient will be mobilizes based on training. The vital signs will be measured before the start of the intervention and the patient's pain will be measured according to the pain guideline (0 to 10). If the vital signs are normal and the patient has a pain score below 5, no nausea, vomiting, no dizziness, no medical prohibition, the mobilization intervention will begin.

Category

Rehabilitation

2

Description
Control group: these patients will be mobilized the day after surgery according to the routine care of the ward.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital of Kashan
Full name of responsible person
Azam Dehghani Firoozabadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafshe
Street address
Ravand Ave., Parastar Blvd.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Esmail Azizi-fini
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for updating data

Contact

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Full name of responsible person
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Student

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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There are no more information.

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