

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Supervised exercise therapy in patients treated with midline incision laparotomy: a clinical trial

Protocol summary

Study aim

The main purpose of our study was to evaluate the effect of postoperative exercise monitoring therapy in midline laparotomy patients and to evaluate the short-term complications of midline laparotomy.

Design

Study on 40 patients, 20 of whom are in the control group. Randomization will be performed with a simple randomization method with parallel, double-blinded.

Settings and conduct

For patients in the exercise therapy intervention group, exercise will be taught twice daily for 15 minutes under supervision. Duration of hospitalization, the time of gas excretion by the patient during the hospitalization period will be recorded by informing the nursing staff. For this evaluation, the end time of surgery will be considered zero minutes. To evaluate patients' performance, patients will be instructed and measured in a 30-second stand-up test. All measurements will be taken the day after surgery as the pre-intervention point and the day of discharge. The patients will be discharged when the pain is controlled with oral medication, the patient is able to tolerate solid food, and the patient is no longer nauseous and had defecation.

Participants/Inclusion and exclusion criteria

Patients aged 20 to 70 years who are literate and have undergone elective or emergency surgery by midline laparotomy incision in the general surgery ward of Loghman Hakim Hospital.

Intervention groups

For patients in the exercise therapy intervention group, stretching exercises, progressive strength, and functional exercises will be performed twice a day for 15 minutes under supervision. While patients are still in the hospital recovering from surgery.

Main outcome variables

The duration of hospitalization, the duration of gas excretion during hospitalization at the time of discharge, and to evaluate patients' performance, a 30-second post-

surgery and 30-day post-surgery test will be measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220430054701N1**

Registration date: **2022-05-11, 1401/02/21**

Registration timing: **prospective**

Last update: **2022-05-11, 1401/02/21**

Update count: **0**

Registration date

2022-05-11, 1401/02/21

Registrant information

Name

Azadeh Hakakzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 9007

Email address

ahakakzade@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Supervised exercise therapy in patients treated with midline incision laparotomy: a clinical trial

Public title

Exercise therapy in midline incision laparotomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients treated with midline incision laparotomy

Exclusion criteria:

Evidence of recurrent or metastatic disease Use of immunosuppressive drugs Use of (ERAS)enhanced recovery after surgery for postoperative care

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients will be based on simple randomization and with the help of accepted methods to generate a random sequence on the web. The site randomizer.org will be used by filling in the information of the number of patients, and two target groups, assigning an equal number in each group and selecting non-duplicate numbers in this plan. Based on the numbers with random sequences generated on the site, patients will be divided into two groups. The intervention group will be the exercise therapy intervention group and group B, which is the group of routine postoperative interventions will be the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The allocation will be concealed by using opaque, sealed envelopes that were consecutively numbered. Apart from the project coordinator, the patients, attending physician of supervised exercise therapy will be blinded to the intervention allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Medicine, Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Arabi Ave., Yemen Blvd., Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-02-09, 1400/11/20

Ethics committee reference number

IR.SBMU.MSP.REC.1400.737

Health conditions studied

1

Description of health condition studied

Evaluation of complications of midline laparotomy surgery

ICD-10 code

Y40-Y84

ICD-10 code description

Complications of medical and surgical care

Primary outcomes

1

Description

Any surgical complication

Timepoint

Immediately after surgery, before discharge and 30 days after surgery

Method of measurement

Patient physical exam by the surgeon

2

Description

Hospitalization duration

Timepoint

Immediately after surgery, before discharge

Method of measurement

Checking the patient files

3

Description

Duration of first gas excretion after surgery

Timepoint

Immediately after surgery

Method of measurement

Inform the nurse ward and register on patient file

Secondary outcomes

1

Description

30 seconds chair stand functional test

Timepoint

Before discharge and 30 days after surgery

Method of measurement

Counting the number of complete repetitions of the standing-sitting cycle

Intervention groups

1

Description

Intervention group: Patients aged 20-70 years treated with elective surgery or emergency with midline laparotomy incision for whom in the exercise therapy intervention group, exercise will be performed twice daily for 15 minutes under supervision during hospitalization

Category

Rehabilitation

2

Description

Control group: Patients aged 20-70 years treated with elective surgery or midline laparotomy incision in the control group, patients will receive routine postoperative support protocol.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Azadeh Hakakzadeh

Street address

Lashkar crossroad, Makhsoos street

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Tehran

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1333635445

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ahakakzade@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Shahid Chamran Highway, Yemen St. - Shahid Arabi St. - Building No. 2 - Fifth Floor

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Hakakzadeh

Position

Non-faculty specialist

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Azadeh Hakakzadeh

Position

non faculty specialist

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fariborz Rashnoo

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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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

The study will continue in later phases and with follow-up in subsequent clinical trial studies with other exercise methods

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available