

# 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1333635445

##### Phone

+98 21 5541 9005

##### Email

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

##### City

Tehran

##### Province

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##### Postal code

1985717443

##### Phone

+98 21 2243 9780

##### Email

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

##### Street address

Shahid Chamran Highway, Yemen St. - Shahid Arabi St.

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##### Province

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Fariborz Rashnoo

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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fariborz.rashno@yahoo.com

**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