

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison number of lymphnode resection in open colectomy vs laparoscopy in colorectal cancer

#### Protocol summary

##### Study aim

Comparison of number of lymphnode resection in open colectomy versus laparoscopy in colorectal cancer

##### Design

A non randomized clinical trial with two intervention group that was not blinded. Based on the trait ratio studied in similar articles in the population, the number of patients was estimated to be about 120 patients.

##### Settings and conduct

This RCT was conducted on all patients admitted to Modarres hospital, Tehran, Iran in 2017 to 2019 who have been diagnosed with colorectal cancer.

##### Participants/Inclusion and exclusion criteria

Patients which had colorectal cancer and needs surgery which admitted in Modarres hospital, Tehran, Iran between years 2018-2020 and

##### Intervention groups

In this prospective study, patients aged 30-60 years who are candidate for colorectal surgery due to colorectal cancer will be included in the study. Patients are divided into two groups of open and laparoscopic based on the type of surgery. For both groups of patients the checklist included demographic information, postoperative pain, duration of hospitalization, infection at site up to 30 day, number of lymph nodes removed in pathology, hemoglobin drop, urinary tract injury and duration the surgery is followed.

##### Main outcome variables

Number of lymphnode removed in pathology, surgical type, hemoglobin drop, infection at site up to 30 day, leak anastomosis, urinary tract injury, duration the surgery, postoperative pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160803029181N10**

Registration date: **2019-12-17, 1398/09/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-17, 1398/09/26**

Update count: **0**

##### Registration date

2019-12-17, 1398/09/26

##### Registrant information

###### Name

Nasser Malekpour Alamdari

###### Name of organization / entity

Shaid Behesht University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2207 4089

###### Email address

nassermalekpour@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-18, 1398/03/28

##### Expected recruitment end date

2021-03-19, 1399/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison number of lymphnode resection in open colectomy vs laparoscopy in colorectal cancer

##### Public title

Comparison number of lymphnode resection in open

colectomy vs laparoscopy in colorectal cancer

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Patients with colorectal cancer

##### **Exclusion criteria:**

#### **Age**

From **30 years** old to **60 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **120**

#### **Randomization (investigator's opinion)**

Not randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Factorial

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shahid Beheshti University of  
Medical Sciences

##### **Street address**

Shahid Beheshti University of Medical Sciences, Arabi  
street, Velenjak

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1998734383

#### **Approval date**

2019-06-18, 1398/03/28

#### **Ethics committee reference number**

IR.SBMU.MSP.REC.1398.256

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Colorectal cancer

#### **ICD-10 code**

C19

#### **ICD-10 code description**

Malignant neoplasm of rectosigmoid junction

## **Primary outcomes**

### 1

#### **Description**

Number of lymphnode resection in surgery

#### **Timepoint**

From the diagnosis of colorectal cancer and time of  
surgery performed

#### **Method of measurement**

Lymph node count in pathology

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Evaluation of the number of lymph  
nodes removed in open surgery in patient with colorectal  
cancer

#### **Category**

Treatment - Surgery

### 2

#### **Description**

Intervention group: Evaluation of the number of lymph  
nodes removed in laparoscopic surgery in patient with  
colorectal cancer

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Beheshti University of Medical Science; Shahid  
Modaress Hospital

##### **Full name of responsible person**

Naser Malekpour

##### **Street address**

Shahid Modares Hospital; Faraz Street; Saadat Abad

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##### **Email**

nassermalekpour@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyyed Ali Ziai

**Street address**

Daneshju Ave, Velenjak

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aliziai@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**

Nasser Malekpour Alamdari

**Position**

Vascular surgeon fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nasser Malekpour Alamdari

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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## Person responsible for updating data

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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 is no further data

**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