

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Ali Ziai

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Daneshju Ave, Velenjak

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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

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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Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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

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