

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

A clinical trial to compare the effectiveness of peritoneal lavage of normal saline with gentamicin-clindamycin on pain relief following laparoscopic colectomy

Protocol summary

Study aim

A clinical trial to compare the effectiveness of peritoneal lavage of normal saline with gentamicin-clindamycin on pain relief following laparoscopic colectomy

Design

Forty patients who were candidates for laparoscopic colectomy, clinical trial with a control group, community-based and pragmatic, parallel groups, double-blind, randomized using table of random numbers

Settings and conduct

Patients candidate for laparoscopic colectomy at the Firoozgar Hospital, Tehran, were chosen. In this double-blind study, the surgeon and assistant who visit the patient after surgery are blinded to the contents of the lavage solution.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients with ASA class one or two, who are candidate for laparoscopic colectomy. Exclusion criteria: Allergy to the drugs studied, history of hypertension, history of uncontrolled diabetes, history of cardiovascular diseases, history of renal failure, history of cirrhosis, and history of smoking or drug abuse.

Intervention groups

The control group are administered peritoneal cavity lavage with 500 ml normal saline. The intervention group receive peritoneal cavity lavage 240 mg gentamicin and 600 mg clindamycin diluted in 500 ml normal saline.

Main outcome variables

Evaluation and comparison of pain relief based on the visual analog scale (VAS) 3, 6, 12, and 24 hours after the intervention between the control and intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180522039782N1**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **prospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Behnood Farazmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8842 9230

Email address

farazmand.b@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2019-12-01, 1398/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of peritoneal lavage of normal saline with gentamicin-clindamycin on

pain relief following laparoscopic colectomy

Public title

The effective of gentamicin-clindamycin on pain relief following laparoscopic colectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patients with ASA class one or two, who are candidate for laparoscopic colectomy

Exclusion criteria:

Allergy to the drugs studied
History of hypertension
History of uncontrolled diabetes
History of cardiovascular diseases
History of renal failure
History of cirrhosis
History of smoking or drug abuse

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Forty patients who are candidates for laparoscopic colectomy are randomly allocated using table of random numbers based on computer programs. To this end, a code is allocated to each of the participants to be assigned into one of the two groups of intervention or control

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients candidate for laparoscopic colectomy at the Firoozgar Hospital, Tehran, were chosen. In this double-blind study, the surgeon and assistant who visit the patient after surgery are blinded to the contents of the lavage solution

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.IUMS.FMD.REC1396.118054

Health conditions studied

1

Description of health condition studied

Colectomy

ICD-10 code

Z90.4

ICD-10 code description

Acquired absence of other parts of digestive tract

Primary outcomes

1

Description

Pain relief

Timepoint

3, 6, 12, and 24 hours after the intervention

Method of measurement

Based on the visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: patients are administered peritoneal cavity lavage with 500 ml normal saline

Category

Treatment - Drugs

2

Description

Intervention group: Patients are administered peritoneal cavity lavage 240 mg gentamicin and 600 mg clindamycin diluted in 500 ml normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Behnood Farazmand

Street address

Firoozgar Hospital, Beh Afarin Street, Karim Khan
Zand Avenue, Valiasr Square

City

Tehran

Province

Tehran

Postal code

14665-354

Phone

+98 21 86709

Email

behnoood@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakoti

Street address

Iran University of Medical Sciences, Shahid Hemmat
Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8842 9230

Email

PR@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Behnood Farazmand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Iran University of Medical Sciences, Shahid Hemmat
Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8842 9230

Email

behnoood@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Resident

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Email

behnoood@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Iran University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results.

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Behnood Farazmand provides the analysis code to the applicants via email: behnoood@gmail.com

What processes are involved for a request to access data/document

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments