

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Hydration deferred fluid limitation combine with norepinephrine infusion on perioperative and post- operative complications during colorectal surgeries

Protocol summary

Summary

The aim of this study was to determine the impact of fluid limitation with norepinephrine infusion versus routine fluid therapy on complications during colorectal surgery and post- operative periods. This study based on randomized sampling, double blind and single center study. Inclusion criteria were: patients suffering from colorectal cancer; age group between 20 to 60 years old; nether evidence of Myocardial infarction during last 6 months nor significant cardiovascular disease; neither use of anticoagulants agent nor coagulopathy. Exclusion criteria were: severe hemodynamic instability; oliguria ; anuria and significant Electrocardiographic changes during surgery. Study population included 168 patients with colorectal cancer who were divided randomly in 2 control and intervention groups; For intervention group: induced fluid limitation with norepinephrine infusion during surgery. For control patients administrated routine fluid therapy during surgery. At the end of surgery patients transfer to intensive care unit and follow up for 2 days. Then the hemodynamic changes, Post-operative complications and duration of hospital admission were compared on both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121120285N1**
Registration date: **2015-02-22, 1393/12/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-22, 1393/12/03

Registrant information

Name

Shervin Malekzadeh

Name of organization / entity

Tehran university of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2828

Email address

shervinmalekzadeh@irimc.org

Recruitment status

Recruitment complete

Funding source

Tehran university of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Hydration deferred fluid limitation combine with norepinephrine infusion on perioperative and post-operative complications during colorectal surgeries

Public title

Impact of fluid limitation combine with norepinephrine infusion during colorectal surgery on perioperative and post-operative complications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria were: patients suffering from colorectal cancer; age group between 20 to 60 years old; nether evidence of Myocardial infarction during last 6 months nor significant cardiovascular disease; neither use of anticoagulants agent nor coagulopathy. Exclusion criteria were: severe hemodynamic instability; oliguria; anuria and significant Electrocardiographic changes during surgery.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **168**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

For the purpose of blinding random allocation was done with other person. Randomization Method: Block randomization was used to equalized the number of patients in both control and intervention groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science

Street address

Ghods St., Keshavarz Blvd Tehran

City

Tehran

Postal code

1417653761

Approval date

2014-06-30, 1393/04/09

Ethics committee reference number

91111074028

Health conditions studied

1

Description of health condition studied

Relation between fluid limitation combine with norepinephrine infusion on perioperative and post-operative complications during colorectal surgeries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hypotension during surgery

Timepoint

During procedure till two days after procedure

Method of measurement

Invasive Blood Pressure monitoring by Arterial Catheter

2

Description

Oliguria

Timepoint

During procedure till two days after procedure

Method of measurement

Urine Output Volume

3

Description

Duration of hospital admission after surgery

Timepoint

Time of discharging from hospital

Method of measurement

According to clinical file

Secondary outcomes

empty

Intervention groups

1

Description

After General anesthesia in control group, routine fluid therapy was administrated.

Category

Treatment - Drugs

2

Description

After General anesthesia in intervention group , fluid limitation combine with norepinephrine infusion (4 micro/kg/h) was administrated.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr Mojgan Rahimi,

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran university of Medical Science

Full name of responsible person

Dr.Mojgan Rahimi

Street address

Ghods St., Keshavarz Blv Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran university of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shervin Malekzadeh

Position

Assistant of Anesthesiology

Other areas of specialty/work

Street address

Ghods St., Keshavarz Blvd Tehran

City

Tehran

Postal code

1417653761

Phone

+98 21 6119 2828

Fax

+98 21 6119 2828

Email

shervinmalekzadeh@irimc.org

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mojgan Rahimi

Position

Assistant Professor

Other areas of specialty/work

Street address

Ghods St., Keshavarz Blvd Tehran

City

Tehran

Postal code

1417653761

Phone

+98 21 6119 2828

Fax

Email

drr_Anesthesist@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shervin Malekzadeh

Position

Assistant of Anesthesiology

Other areas of specialty/work

Street address

Ghods St., Keshavarz Blvd Tehran

City

Tehran

Postal code

1417653761

Phone

+98 21 6119 2828

Fax

+98 21 6119 2828

Email

shervinmalekzadeh@irimc.org;

shervin_m1982@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty