

# 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**

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#### Person responsible for scientific inquiries

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Dr. Mojgan Rahimi

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Assistant Professor

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#### Person responsible for updating data

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Assistant of Anesthesiology

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#### 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*