

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The Effect of Intravenous Fluid Therapy before Colonoscopy on Arterial Blood Oxygen Saturation, Heart Rate and Patients' Blood Pressure

Protocol summary

Study aim

The aim of this study was to the effect of intravenous fluid therapy before colonoscopy on arterial blood oxygen saturation, heart rate and blood pressure of patients.

Design

This study was a randomized clinical trial with two groups (intervention and control), pre and post-test design, and not-blinded.

Settings and conduct

This study was conducted on 60 patients who referred to Ghaem hospital of Mashhad that were randomly divided into two groups (n = 30).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Lower gastrointestinal disorders.
Exclusion criteria: Severe bleeding during the study.

Intervention groups

Intervention group: in intervention group, patients were received one liter of 1/3-2/3, one hour before colonoscopy. Control group: in control group, was conducted routine colonoscopy.

Main outcome variables

Arterial Blood Oxygen Saturation; Heart Rate; Blood Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181010041302N1**
Registration date: **2018-11-02, 1397/08/11**
Registration timing: **retrospective**

Last update: **2018-11-02, 1397/08/11**

Update count: **0**

Registration date

2018-11-02, 1397/08/11

Registrant information

Name

Mohammad Rajabpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2016-10-31, 1395/08/10

Actual recruitment start date

2016-06-30, 1395/04/10

Actual recruitment end date

2016-10-31, 1395/08/10

Trial completion date

2016-12-30, 1395/10/10

Scientific title

The Effect of Intravenous Fluid Therapy before Colonoscopy on Arterial Blood Oxygen Saturation, Heart Rate and Patients' Blood Pressure

Public title

The Effect of Intravenous Fluid Therapy on Blood Circulation Indexes of Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Lower gastrointestinal disorders

Exclusion criteria:

Severe bleeding during the study

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients divided to intervention and control group with simple randomization method (with lottery of sampling days).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The patients divided to intervention and control group with simple randomization method (with lottery of sampling days).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraihy Building, University St

City

Mashhad

Province

Razavi Khorasan

Postal code

9781414878

Approval date

2015-12-25, 1394/10/04

Ethics committee reference number

IR.MUMS.REC.94.261

Health conditions studied

1

Description of health condition studied

Arterial Blood Oxygen Saturation

ICD-10 code

-

ICD-10 code description

-

2

Description of health condition studied

Heart Rate

ICD-10 code

-

ICD-10 code description

-

3

Description of health condition studied

Blood Pressure

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Arterial Blood Oxygen

Timepoint

Before the intervention and the 1, 3, 5, 9 and 10 minute after colonoscopy

Method of measurement

Researcher-made Checklist for the Control of Cardiovascular Status

2

Description

Heart Rate

Timepoint

Before the intervention and the 1, 3, 5, 9 and 10 minute after colonoscopy

Method of measurement

Researcher-made Checklist for the Control of Cardiovascular Status

3

Description

Blood Pressure

Timepoint

Before the intervention and the 1, 3, 5, 9 and 10 minute after colonoscopy

Method of measurement

Researcher-made Checklist for the Control of Cardiovascular Status

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in intervention group, patients were received one liter of 1/3-2/3, one hour before colonoscopy.

Category

Prevention

2

Description

Control group: in control group, was conducted routine colonoscopy.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mostafa Dastani

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Endoscopy Department, GHAem Hospital, Ahmad Abad St, Dr Shariati Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Rajabpoor

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Yes - There is 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 study report published in the dissertation form and article for researcher.

When the data will become available and for how long

The start of access is 6 months after the announcement of the results.

To whom data/document is available

Researchers at university centers

Under which criteria data/document could be used

Data is authorized only with permission from the author of the articles and with the source.

From where data/document is obtainable

Mohammad Rajabpoor, Paramedical School, Contact Number: 00989158341840, Email: Rajabpoor.m@bums.ac.ir

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

After submitting a request, the request is reviewed and, if the request is accepted, is answered within 1 month.

Comments