

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative evaluation of the effect of two different fluid therapy regimen (crystalloid VS crystalloid + colloid) on the speed of bowel motility return after gastrointestinal resection & anastomosis surgery

Protocol summary

Summary

Further studies are needed in the field of volume and method of fluid therapy in patients having intra-abdominal surgery. This research is also in this context and its purpose is to make a comparison between two different protocols of fluid therapy during surgery, being crystalloid alone and crystalloid-colloid fluid composition during resection and anastomosis surgery of gastrointestinal tract and examining its effect on speed of gastrointestinal motility return after the surgery. For this purpose, in a prospective randomized double blinded clinical trial study, one hundred candidates of gastrointestinal resection & anastomosis will be enrolled in the study. The chosen patients would be 18 to 60 years old and of physical class of ASA I-III. Patients with serious insufficiency in vital organs (such as heart, liver, lungs etc) and genito-urinary diseases will not be included in the study. The selected patients divided randomly in two groups will be put under the aforementioned protocols of fluid therapy (group A) crystalloid, (group B) crystalloid + colloid), during surgery and anesthesia, then their effects on speed of gastrointestinal motility return and incidence of side effects such as nausea and vomiting, leaking from anastomosis site and ileus in the postoperative period shall be evaluated and compared. Also, patients will be prescribed with epidural pumps and local anesthetic drugs for post surgical analgesia; they are excluded from the study in the case of opioid drugs use for treatment of pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090711398N7**

Registration date: **2014-11-30, 1393/09/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-30, 1393/09/09

Registrant information

Name

Mohammad Reza Ghodrati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

m-ghodrati@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research deputy of Iran University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the effect of two different fluid therapy regimen (crystalloid VS crystalloid + colloid) on the speed of bowel motility return after gastrointestinal resection & anastomosis surgery

Public title

Comparative evaluation of the effect of two different fluid therapy regimen on the bowel motility return after surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients candidated for resection & anastomosis of gastrointestinal surgery; Age between 18 - 60 years old; Patients with ASA physical status class I-III; Having consent for entry. Exclusion criteria: Age less than 18 & more than 60; Patients with ASA physical status over than III; Pregnant females; Patients with acute or chronic uncompensated cardiac insufficiency; Known coagulopathy; Hepatic insufficiency (2-3 times increase in liver enzymes); Renal insufficiency (more than 50% rise in creatinine); Known gastroparesis & bowel motility disorders; Fatty patients with BMI over than 35

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Main University building, Qods St. Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2013-09-07, 1392/06/16

Ethics committee reference number

1190/130/92/3

Health conditions studied

1

Description of health condition studied

Ileus

ICD-10 code

K-56.0

ICD-10 code description

Paralytic ileus

Primary outcomes

1

Description

Ileus

Timepoint

Day after intervention

Method of measurement

Based on questionnaire

Secondary outcomes

1

Description

Nausea & Vomiting

Timepoint

Day after intervention

Method of measurement

Based on questionnaire

2

Description

Anastomosis leak

Timepoint

Day after intervention

Method of measurement

Based on clinical chart documents

3

Description

Dehiscence

Timepoint

From day after intervention

Method of measurement

Based on clinical observation

Intervention groups

1

Description

Intervention group: For the fluid therapy of the patients of this group, we will use a combination of crystalloid & colloid fluids. Where, colloid will be used to replace the third space loss and bleeding until reaching the transfusion limit, and crystalloid for the replacing the rest of the fluid needs.

Category

Treatment - Other

2**Description**

In control group: Total calculated fluid need of patients will be replaced with crystalloid (normal saline & ringer lactate in 50:50 ratio)

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Firoozgar Hospital

Full name of responsible person

Hosein Reza Dehghan MD.

Street address

Anesthesiology department, Firoozgar hospital, Beh-afarin St, Karim Khan Av.

City

Tehran

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Research Deputy of Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Moosavi MD.

Street address

Hemmat highway, between Chamran & Sheykh Fazlollah

City

Tehran

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

Yes

Title of funding source

Research Deputy of Iran University of Medical Sciences

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**

Iran University of Medical Sciences

Full name of responsible person

Hosein Reza Dehghan MD.

Position

Anesthesia Resident

Other areas of specialty/work**Street address**

Anesthesiology Department, Firoozgar Hospital, Beh-afarin St, Karim Khan Av.

City

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax**Email**

dhoseinreza@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Anesthesiologist, Assistant Professor

Other areas of specialty/work**Street address**

Anesthesiology Department, Firoozgar Hospital, Beh-afarin St, Karim Khan Av.

City

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax**Email**

mrghodrati@yahoo.comghodrati.mr@iums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Hosein Reza Dehghan MD.

Position

Anesthesia Resident

Other areas of specialty/work**Street address**

Anesthesia department, Firoozghar hospital, Beh-afarin St. Karim Khan Av.

City

Tehran

Postal code
Phone
Fax
Email
dhoseinreza@gmail.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