Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 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

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Name of organization / entity

Iran University of Medical Sciences

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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/د

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 questionnare

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 centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Hosein Reza Dehghan MD.
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Anesthesiology department, Firoozgar hospital, Behafarin St, Karim Khan Av.
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Sponsors / Funding sources

1

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

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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