

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison hospital outcome of early oral feeding and late oral feeding in elective intestinal anastomosis in surgical cases

Protocol summary

Summary

The purpose of this study is to compare inpatient outcomes in two types of early and late oral nutrition in surgical intestinal anastomosis cases. The study will be conducted single-blind in 60 patients who are operated for intestinal anastomosis. The patients will be divided into two groups randomly. Inclusion criteria for the study would be intestinal anastomosis in elective surgical patients, no associated surgical or medical disease, patient's consent to the study and no associated malnutrition. Exclusion criteria would be age over 75 years or less than 15 years of age, associated malnutrition, severe associated diseases, emergent cases, intestinal obstruction or peritonitis. The studied intervention would be initiation of post-operative oral nutrition. The oral nutrition will be initiated after 24 hours in the first group and after 4 days in the second group. The studied outcomes would be abdominal pain, abdominal distension, vomiting and nausea, duration of admission and early complications including leak & dehiscence of anastomosis, mesenteric emboli and wound infection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108067238N1**
Registration date: **2011-09-10, 1390/06/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-09-10, 1390/06/19

Registrant information

Name

Yaghoub Oroji

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison hospital outcome of early oral feeding and late oral feeding in elective intestinal anastomosis in surgical cases

Public title

Comparison hospital outcome of early oral feeding and late oral feeding in elective intestinal anastomosis in surgical cases

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: intestinal anastomosis in elective surgical patients; no associated surgical or medical disease; patient's consent to the study; no associated malnutrition
Exclusion criteria: age over 75 years or less

than 15 years of age; associated malnutrition; severe associated diseases; emergent cases, intestinal obstruction or peritonitis

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht St.

City

Tabriz

Postal code

Approval date

2011-06-28, 1390/04/07

Ethics committee reference number

42755/5

Health conditions studied

1

Description of health condition studied

Need for intestinal anastomosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Distension

Timepoint

First to fifth post-operative days

Method of measurement

History & Physical Examination

Secondary outcomes

1

Description

Abdominal pain

Timepoint

First to fifth post-operative days

Method of measurement

History

2

Description

Vomitting & nausea

Timepoint

First to fifth post-operative days

Method of measurement

History

3

Description

Duration of admission

Timepoint

Days in hospital

Method of measurement

Counting days

4

Description

Early complications

Timepoint

First to fifth post-operative days

Method of measurement

History, physical examination and diagnostic techniques

Intervention groups

1

Description

Initiation of oral nutrition at first 24 hours in first group

Category

Other

2

Description

Initiation of oral nutrition after 4 days in second group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Street address

City

Tabriz

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Street address

City

Tabriz

3

Recruitment center

Name of recruitment center

Amir-al-Momenin Hospital

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tanriz University of Medical Sciences

Full name of responsible person

Dr. A.R. barband

Street address

Sina Hospital

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tanriz 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

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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