Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A Randomized Controlled Trial evaluating the Efficacy of Early Postoperative Oral Feeding in Patients with Gastresophageal Tumors Undergoing Surgery

Protocol summary

Summary

Our study aim to investigate the safety of starting early oral feeding in patients undergoing surgical resection of upper gastrointestinal malignancies and compare its benefits with final outcomes of those patients who began oral feeding later on the 4th postoperative days. A randomized controlled trial is conducted to enroll patients with diagnosis of esophageal or gastric malignancies in Cancer Institute of Imam Khomeini Hospital and Shariti Hospital and assign them into early oral feeding (EOF) group or late oral feeding (LOF group). Postoperative outcomes and surgical complications is going to be compared between the two groups. Inclusion Criteria includes malignancy of Esophagus and Stomach, Major surgery for patient management, and agreement to enter the study. Patients who expires within early postoperative period, proved preoperative infection, have a history of pelvic or abdominal radiation, or already on immunosupressive agents are excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204122982N8**
Registration date: **2012-10-16, 1391/07/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-10-16, 1391/07/25

Registrant information

Name

Zhamak Khorgami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8490 2450

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-11-03, 1390/08/12

Expected recruitment end date

2012-07-30, 1391/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized Controlled Trial evaluating the Efficacy of Early Postoperative Oral Feeding in Patients with Gastresophageal Tumors Undergoing Surgery

Public title

Early Oral Feeding in Gastresophageal Tumors Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Malignancy of Esophagus and Stomach, Major surgery for patient management, and agreement to enter the study. Exclusion Criteria: Expiration within early postoperative period, proved preoperative infection, history of pelvic or abdominal radiation, already on immunosupressive agents.

Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **138**
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
Research Deputy, Faculty of Medicine, Poursina Street, Keshavarz Blvd
City
Tehran
Postal code
Approval date
2012-03-20, 1391/01/01
Ethics committee reference number
54825/130/90/ɔ

Health conditions studied

1

Description of health condition studied
Gastric Tumor
ICD-10 code
C16.9
ICD-10 code description
Malignant neoplasm of stomach

2

Description of health condition studied
Cardiac Tumor
ICD-10 code
C16.0
ICD-10 code description
Malignant neoplasm of cardia

3

Description of health condition studied
Esophageal Cancer
ICD-10 code
C15
ICD-10 code description
Malignant neoplasm of esophagus

Primary outcomes

1

Description
Vomiting
Timepoint
Everyday
Method of measurement
Asking the patient

2

Description
Soft Diet
Timepoint
Days tolerated
Method of measurement
Asking the patient

3

Description
Length of Administration > 1000cc Serum daily
Timepoint
Everyday
Method of measurement
Patient's Medical Records

Secondary outcomes

1

Description
Hospital Stay
Timepoint
At Discharge
Method of measurement
Patient's Medical Records

2

Description
Postoperative Complication
Timepoint
Everyday
Method of measurement
Examination, History and Medical Records

3

Description
Re-hospitalization
Timepoint
After Discharge
Method of measurement
Medical Records

Intervention groups

1

Description
On the basis of the protocol, in patients of early oral feeding group (referred to as Case group) a liquid regimen was started in 24 to 48 hours after the surgery. The regimen contained 50 cc tea combined with two sugar cube every 8 hours while the patient still had nasogastric (NG) tube. NG tube was removed when its secretion decreased to less than 500 cc per day. The liquid regimen increased in volume and in case of patient's toleration a regular soft diet was then started after 24 hours of liquid initiation.
Category
Rehabilitation

2

Description
In traditional oral feeding group referred to as Control group, oral feeding was started following five postoperative days in case of either audible bowel sounds, passage of flatus or bowel habits.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Surgery/ Shariati Hospital
Full name of responsible person
Zhamak Khorgami
Street address
Shariati Hospital- North Kargar Ave-
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Shahin Akhondzadeh
Street address
Medical School Research Affairs, Poorsina Street, Keshavarz Blv
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 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
Tehran University of Medical Sciences
Full name of responsible person
Zhamak Khorgami
Position
General Surgeon/ Assistant Professor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Habibollah Mahmoodzadeh
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General Surgeon and Fellowship of Surgical Oncology/ Assistant Professor
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Cancer Institute, Imam Khomeini Hospital, Keshavarz Blv
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Web page address

Person responsible for updating data

Contact

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