

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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 immunosuppressive 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)

Phone

+98 21 8490 2450

Email address

khorgami@tums.ac.ir

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 immunosuppressive 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
54825/130/90/3

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

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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

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

Street address

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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

Position

General Surgeon and Fellowship of Surgical Oncology/
Assistant Professor

Other areas of specialty/work

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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