# 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 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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**Web page address**

## Person responsible for scientific inquiries

**Contact**
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**Full name of responsible person**
Habibollah Mahmoodzadeh
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General Surgeon and Fellowship of Surgical Oncology/ Assistant Professor
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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*