Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of beginning time of oral feeding on the length of hospitalization, risk of rebleeding and nutritional status of patients with upper gastrointestinal bleeding caused by peptic ulcers and erosive diseases

Protocol summary

Study aim

This study was designed to investigate the effect of the time of initiation of oral feeding on the duration of hospitalization, the risk of rebleeding and the nutritional status of patients with upper gastrointestinal bleeding caused by peptic ulcer and erosive gastrointestinal diseases.

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, on 166 patients. To avoid selection bias in the present study, random permutations allocation method

Settings and conduct

Patient admission will be done at Rasool Akram Hospital. Patients who are eligible to participate in the study and are willing to participate in the study are randomly divided into two groups after undergoing medical treatment. One group of people will fast for 24 hours and the other group will fast for 48 hours after the treatment. Then they will be fed with clear liquids, full liquids, soft food, light food, and regular food respectively.

Participants/Inclusion and exclusion criteria

Patients with peptic ulcer and upper gastrointestinal erosives who have gastrointestinal bleeding, according to Forrest's classification in the category of ulcer with active bleeding, a visible vessel without bleeding or sticky clot, with an age of 18 to 65 years and a BMI between 18.5 to 35. People hospitalized in the intensive care unit, bleeding due to reasons other than peptic ulcer and digestive erosive and bleeding due to caustic substances will not be included in the study.

Intervention groups

The intervention group will receive oral nutrition after 24 hours and the control group after 48 hours of fasting after bleeding treatment.

Main outcome variables

Incidence of rebleeding; duration of hospitalization; nutritional risk screening; arm circumference; serum albumin; total serum protein; Gastrointestinal Clinical Symptoms Questionnaire score; patient satisfaction with the diet plan and pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N63**
Registration date: **2023-08-20, 1402/05/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-20, 1402/05/29**
Update count: **0**

Registration date

2023-08-20, 1402/05/29

Registrant information

Name
Farzad Shidfar
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8862 2755
Email address
shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-13, 1402/05/22

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of beginning time of oral feeding on the length of hospitalization, risk of rebleeding and nutritional status of patients with upper gastrointestinal bleeding caused by peptic ulcers and erosive diseases

Public title

Initiation of oral feeding in upper gastrointestinal bleeding

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-65 years old Patients with bleeding due to peptic ulcer, both stomach and duodenum, and bleeding due to erosive esophagus, stomach and duodenum Patients with active bleeding, visible vessel without active bleeding and adherent clot based on Forrest's classification and endoscopic diagnosis Patients with a BMI between 18.5-35

Exclusion criteria:

Patients admitted to the intensive care unit Patients with bleeding due to varicose veins, caustic substances Patients with gastrointestinal cancers Patients with clean base and flat pigmented spot ulcers Patients whose bleeding has not been treated Patients with gastrointestinal surgeries such as bariatric surgeries Patients who have been kept fasting for other reasons pregnant women Unwillingness to continue cooperation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **166**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants are individually assigned to two groups using R programming language statistical software by random permutations. The reason for using this method is that the distribution of both peptic ulcer disease and erosive disease is similar in two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committees of Iran university of medical sciences

Street address

Iran University of Medical Sciences, Tehran, Iran. Shahid Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-08-08, 1402/05/17

Ethics committee reference number

IR.IUMS.REC.1402.429

Health conditions studied

1

Description of health condition studied

Peptic ulcer with bleeding

ICD-10 code

K27.4

ICD-10 code description

Chronic or unspecified peptic ulcer, site unspecified, with hemorrhage

2

Description of health condition studied

Acute gastritis with bleeding

ICD-10 code

K29.01

ICD-10 code description

Acute gastritis with bleeding

3

Description of health condition studied

Ulcer of esophagus with bleeding

ICD-10 code

K22.11

ICD-10 code description

Ulcer of esophagus with bleeding

4

Description of health condition studied
Duodenitis with bleeding
ICD-10 code
K29.81
ICD-10 code description
Duodenitis with bleeding

Primary outcomes

1

Description
Occurrence of rebleeding within 7 days after endoscopic therapy
Timepoint
Day 7 after receiving endoscopic therapy
Method of measurement
Questionnaire with confirmation of diagnosis by endoscopy

Secondary outcomes

1

Description
Occurrence of rebleeding within 14 days after treatment
Timepoint
Day 14
Method of measurement
Questionnaire with confirmation of endoscopic diagnosis

2

Description
Occurrence of rebleeding within 30 days after treatment
Timepoint
Day 30
Method of measurement
Questionnaire with confirmation of endoscopic diagnosis

3

Description
Body weight
Timepoint
The beginning of the study, the time of discharge from the hospital, the end of the study
Method of measurement
Digital scale with 100 gram accuracy

4

Description
Duration of hospitalization after treatment
Timepoint
When discharged from the hospital
Method of measurement
Using the patient's medical record

5

Description
Nutritional status of the patient
Timepoint
The beginning of the study, the time of discharge from the hospital, the end of the study
Method of measurement
"Nutritional risk screening-2002" questionnaire

6

Description
Body mass index
Timepoint
The beginning of the study, the time of discharge from the hospital, at the end of the study
Method of measurement
Quetelet equation

7

Description
Arm circumference
Timepoint
The beginning of the study, the time of discharge from the hospital, at the end of the study
Method of measurement
tape measure

8

Description
Serum albumin
Timepoint
The beginning of the study, the time of discharge from the hospital, at the end of the study
Method of measurement
Blood sample

9

Description
Serum total protein
Timepoint
The beginning of the study, the time of discharge from the hospital, at the end of the study
Method of measurement
Blood sample

10

Description
Gastrointestinal clinical symptoms
Timepoint
During hospitalization, at the end of the study
Method of measurement
"Gastrointestinal Symptom Rating Scale (GSRS)" questionnaire

11

Description
The level of patient satisfaction with the diet plan during

hospitalization

Timepoint

During hospitalization

Method of measurement

questionnaire

12

Description

Pain score

Timepoint

At the beginning of the study, during hospitalization, at the end of the study

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: The intervention group, which includes 83 people, will be kept fasting for 24 hours after the endoscopy, if they meet the conditions to enter the study, and during this period the patient will receive injectable serums under the supervision of the attending physician. . After the fasting period, patients will be fed first with clear liquids for 6 hours, then with full liquids for 6 hours, and then with soft food for 12 hours. On the second day, the patients will be fed with light food that has little spices, fiber and fat and is non-flatulent, and on the third day, they will receive normal food, and after the patient tolerates the normal food, he can be discharged according to the nutritionist. Then, the patient will be followed up for a period of thirty days from entering the study.

Category

Rehabilitation

2

Description

Control group: The control group, which includes 83 people, will be kept fasting for 48 hours after the endoscopy, if they meet the conditions for entering the study, and during this period, the patient will receive injectable serums under the supervision of the attending physician. After the fasting period, patients will be fed first with clear liquids for 6 hours, then with solid liquids for 6 hours, and then with soft food for 12 hours. On the second day, the patients will be fed with light food that has little spices, fiber and fat and is non-flatulent, and on the third day, they will receive normal food, and after the patient tolerates the normal food, he/she can be discharged according to the nutritionist. Then, the patient will be followed up for a period of thirty days from entering the study.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Mohsen Masoodi

Street address

Sattar Khan St, Niyayesh St, corner of Mansouri St, Rasoul Akram hospital

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

Rasoolhospital@iums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2030

Email

rezafalak@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farzad Shidfar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition science, School of Health, Iran University of Medical Sciences, Next to the Milad Tower, Shahid Hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2755
Fax
+98 21 8862 2533
Email
shidfar.f@iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farzad Shidfar
Position
faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition science, School of Health, Iran University of Medical Sciences, next to the Milad Tower, Shahid Hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2755
Fax
+98 21 8862 2533
Email
shidfar.f@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farzad Shidfar
Position
faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition science, School of Health, Iran University of Medical Sciences, Next to the Milad tower, Shahid Hemmat highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8862 2755
Fax
+98 21 8862 2533
Email
shidfar.f@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
According to the ethical protocol, personal information of volunteers is considered confidential.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Rebleeding time, length of stay in the hospital, score of questionnaires used, anthropometric data, blood variables
When the data will become available and for how long
From September, 2024
To whom data/document is available
The presenter and main collaborator
Under which criteria data/document could be used
If the university officially requests

From where data/document is obtainable

The presenter and main collaborator

What processes are involved for a request to access data/document

Official application through the university to the administrator

Comments