

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

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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.
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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

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Rasoolhospital@iums.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

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

shidfar.f@iums.ac.ir

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

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Email

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