

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effects of bougie, Balloon dilatation and incisional therapy on dysphagia in patients with benign esophageal stricture secondary to caustic injury

Protocol summary

Study aim

Comparing the treatments of bougie, Balloon dilatation and incisional therapy in patients with benign esophageal stricture secondary to caustic injury

Design

A clinical trial, with three intervention groups, with parallel groups, unblinded, randomized, phase 2 on 75 patients, randomized with Sealed envelope software.

Settings and conduct

This intervention will be implemented in the endoscopy department of Taleghani Hospital in Tehran. The participants will be randomly placed in three groups for interventions to remove esophageal stricture. Interventions will include bogie, balloon dilatation and shear therapy. All patients will be evaluated before the intervention, one month, three months and six months after the intervention in terms of clinical success, technical success, improvement of quality of life and occurrence of complications.

Participants/Inclusion and exclusion criteria

Inclusion criteria: inability to swallow, difficulty in swallowing, stenosis due to burn injury. Exclusion criteria: achalasia, esophageal cancer, INR>1.5, PLT<50,000, hemodynamic instability, eosinophilic esophagitis, esophageal surgery in the past month, need for surgery

Intervention groups

Intervention groups: Patients initially undergo endoscopy and barium swallow. Then each group is subjected to one of the bougie, balloon or incisional therapy

Main outcome variables

Dysphagia improvement, technical improvement, quality of life, body mass index, complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230425057990N2**

Registration date: **2023-11-14, 1402/08/23**

Registration timing: **prospective**

Last update: **2023-11-14, 1402/08/23**

Update count: **0**

Registration date

2023-11-14, 1402/08/23

Registrant information

Name

Saeed Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2459 6000

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of bougie, Balloon dilatation and

incisional therapy on dysphagia in patients with benign esophageal stricture secondary to caustic injury

Public title
The effect of endoscopic treatments in the treatment of benign esophageal stricture

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Unable to swallow Difficulty to swallow Benign esophageal stricture secondary to caustic injury
Exclusion criteria:
achalasia Untreated reflux Esophageal surgery during the last month Patients needing surgery

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are assigned to two groups using the random block method. The number of blocks will be 6 and in each block 4 patients will be included in the study order. Random allocation of blocks of patients to three treatment groups will be done through Sealed Envelope online software. The randomized list of blocks will be placed in sealed envelopes and will be provided to prescribers on a daily basis.

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 committee in research of research institute for gastroenterology and liver disease
Street address
Arabi street, Velenjak
City
Tehran
Province

Tehran
Postal code
1985717443
Approval date
2023-09-04, 1402/06/13
Ethics committee reference number
IR.SBMU.RIGLD.REC.1402.005

Health conditions studied

1

Description of health condition studied

benign esophageal stricture

ICD-10 code

K22.2

ICD-10 code description

Esophageal obstruction

Primary outcomes

1

Description

Technical success

Timepoint

Before the intervention, one month, three months and six months after the intervention

Method of measurement

Based of lumen diameter with residual stenosis less than 30%

2

Description

Technical success

Timepoint

Before the intervention, one month, three months and six months after the intervention

Method of measurement

Improvement of dysphagia symptoms

Secondary outcomes

1

Description

Generic Quality of life

Timepoint

Before the intervention, one month, three months and six months after the intervention

Method of measurement

EuroQol-5D (EQ-5D) index

2

Description

Physically quality of life

Timepoint

Before the intervention, one month, three months and six months after the intervention

Method of measurement

body mass index

3

Description

complication

Timepoint

up to 6 hours after the intervention

Method of measurement

Physical examination and history

Intervention groups

1

Description

Intervention group: bougie-For this group of patients, we start with 7 to 9 mm bougie. Then, according to the response to the treatment, we increase the size of the bogie up to 13-15 mm in three stages (1-3 months apart) to control the patient's symptoms (dysphagia).

Category

Treatment - Devices

2

Description

Intervention group: Balloon dilatation-For patients in this group, we start with a 7 to 9 mm balloon and increase it to 15 mm to control the patient's symptoms (dysphagia). At each stage (within a time interval of one to three months), we will have up to three numbers of size increase.

Category

Treatment - Devices

3

Description

Intervention group: incisional therapy-For patients in this group, cutting with a special knife is used to improve the esophageal stricture.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Endoscopy ward, Taleghani Hospital

Full name of responsible person

Amir Sadeghi

Street address

Arabi street, Velenjak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ramyar Zaman Golzari

Position

Gastroenterologist assistant

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Title and more details about the data/document

Only the information related to the study protocol, statistical analysis plan and clinical study report will be made available to the requestors (and not publicly) to other researchers for guidance for further studies.

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Researchers, students and professors in the field of gastroenterology

Under which criteria data/document could be used

For use in further research and if the source is cited

From where data/document is obtainable

corresponding author Dr. Saeed Abdi
saeedabdi75@yahoo.com

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

Send a request via email to the responsible author and mention the reason for the request and how to use the data

Comments