

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of early repeated dilatations in the prevention of esophageal stricture in children with caustic substance ingestion

Protocol summary

Study aim

Determining the effect of early repeated dilatations in the prevention of esophageal stricture in children with caustic substance ingestion

Design

Clinical trial, parallel groups, phase 3, on 30 patients. The randomization will be done by the random number table method through the website <http://www.graphpad.com/quickcalcs/index.cfm>.

Settings and conduct

This study will be conducted with the aim of determining the effect of early repeated dilatations in preventing esophageal stricture in children with caustic ingestion in Akbar Hospital, Mashhad. One group of patients undergo endoscopy and dilatation of esophageal stricture by endoscopic method every week for five sessions and the patients in the other group, like the patients in the previous group, undergo endoscopy and dilatation of the esophageal stricture by endoscopic method for five sessions at intervals of two weeks. Disease symptoms will be assessed at the beginning and end of the intervention through endoscopy. The names of the groups will be recorded as A and B in the data sheet.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Caustic esophageal stricture based on barium swallow study or clinical examination, Consent for participation by the patient or his guardian. Exclusion criteria: Normal upper GI.

Intervention groups

Intervention group1: Patients in the intervention group1 undergo endoscopy and dilatation of esophageal stricture by endoscopic method every week for five sessions. Intervention group2: The patients of the Intervention group2, like the patients of the intervention group1, undergo endoscopy and dilatation of the esophageal stricture by endoscopic method for five sessions at intervals of two weeks.

Main outcome variables

The main outcome variable will be esophageal dilatation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230410057870N1**

Registration date: **2023-05-03, 1402/02/13**

Registration timing: **prospective**

Last update: **2023-05-03, 1402/02/13**

Update count: **0**

Registration date

2023-05-03, 1402/02/13

Registrant information

Name

Nadia Danaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3332 1078

Email address

danaein4001@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of early repeated dilatations in the prevention of esophageal stricture in children with caustic substance ingestion

Public title

Effect of early repeated dilatations in the prevention of esophageal stricture with caustic substance ingestion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Caustic esophageal stricture based on barium swallow study or clinical examination Consent for participation by the patient or his guardian

Exclusion criteria:

Upper GI normality

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups, dilation once a week and once every two weeks. Random numbers table is used for randomization. In order to use random numbers table, it will be determined first to read the numbers in the table, then the numbers are considered for different groups. We put our hands on one of the numbers and move in one of the predetermined directions and assign the numbers to the desired 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 committee of Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

34591375

Approval date

2022-10-24, 1401/08/02

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.704

Health conditions studied

1

Description of health condition studied

Caustic esophageal stricture

ICD-10 code

T28.1

ICD-10 code description

Burn of esophagus

Primary outcomes

1

Description

Dilatation

Timepoint

Every weeks after starting the study

Method of measurement

Endoscopy

Secondary outcomes

1

Description

Dysphagia

Timepoint

Once every week

Method of measurement

Endoscopy

Intervention groups

1

Description

Intervention group1: Patients in the intervention group1 undergo endoscopy and dilatation of esophageal stricture by endoscopic method every week for five sessions.

Category

Treatment - Other

2

Description

Control group2: The patients of the control group2, like the patients of the intervention group1, undergo endoscopy and dilatation of the esophageal stricture by

endoscopic method for five sessions at intervals of two weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Hospital

Full name of responsible person

Nadia Danaee

Street address

Akbar Hospital, Kaveh Blvd, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3871 3801

Email

Danaein4001@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayouri Mobarhan

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

34591375

Phone

+98 51 3841 1538

Email

vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Nadia Danaee

Position

Fellows in Training

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Akbar Hospital, Kaveh Blvd, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3871 3801

Email

Danaein4001@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nadia Danaee

Position

Fellows in Training

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Akbar Hospital, Kaveh Blvd, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3871 3801

Email

Danaein4001@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nadia Danaee

Position

Fellows in Training

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Akbar Hospital, Kaveh Blvd, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3871 3801

Email

Danaein4001@mums.ac.ir

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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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