Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 ingestio

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

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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

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Mashhad

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Razavi Khorasan

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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

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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

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Person responsible for scientific inquiries

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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
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