Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluating the effect of local Mitomycin C jelly on esophageal stricture caused by caustic ingestion

Protocol summary

Study aim
To assess the effect of local Mitomycin C on outcome of caustic esophageal stricture

Design
The trial is a randomized, single-blinded, phase 3 with a control group. The calculated sample size is 40 patients (20 patients for each group). Randomization will be performed using the block method by randomiztion.com website. The allocation concealment was done using opaque, sequentially numbered and sealed envelopes.

Settings and conduct
This study is performed in the Pediatric Gastroenterology Referral Center in Akbar Pediatric Hospital, Mashhad, Iran. After obtaining informed consent, an envelop will be dedicated to each patient. Endoscopic dilatation of esophageal stricture will be performed for all patients. Then, for the patients of the intervention group, mitomycin gel is applied endoscopically to the site of mucosal rupture.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All children and adolescent below 21 years, caustic esophageal stricture based on barium swallow study or clinical examination, consent for participation by the patient or his guardian Exclusion criteria: history of previous esophageal surgery

Intervention groups
Intervention group: Application of local mitomycin gel(from KOREA UNITED PHARM INC.) by endoscopy at the site of mucosal rupture, with a volume of 5 cc and a dose of 0.4 mg per cc, 5 times during the study with an interval of at least two weeks. Control group: Patients in the control group do not receive this medication after dilatation.

Main outcome variables
Dysphagia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201116049399N1**
Registration date: **2020-12-31, 1399/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-31, 1399/10/11**
Update count: **0**

Registration date
2020-12-31, 1399/10/11

Registrant information

Name
Fatemeh Basirinejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3605 7487

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-30, 1399/09/10

Expected recruitment end date
2021-05-10, 1400/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of local Mitomycin C jelly on esophageal stricture caused by caustic ingestion

Public title
Effect of local Mitomycin C in caustic esophageal stricture
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients under 21-year-old Caustic ingestion Esophageal stricture based on barium swallow study or clinical examination Informed consent of patients or his guardian
Exclusion criteria:
Previous esophageal surgery
Age
To **21 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
To generate a random sequence, the block method will be applied using random block size of 4 through the website www.randomization.com. Then the produced sequence will be located in sealed opaque envelopes and finally numbered by the methodologist sequentially.
Blinding (investigator's opinion)
Single blinded
Blinding description
Data analyser is blinded to the group allocation. The groups are coded using A and B letters.
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, Ghoresishi Building, Daneshgah street, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2020-11-15, 1399/08/25
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.466

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
Dysphagia
Timepoint
Every two weeks after starting the study
Method of measurement
Clinical grading

2

Description
Number of Dilatation
Timepoint
Every two weeks after starting the study
Method of measurement
The number of performed procedure

Secondary outcomes

1

Description
Weight
Timepoint
every two weeks after starting the study
Method of measurement
ADE pediatric scale with 1 gram acuity

Intervention groups

1

Description
Intervention group: Patients who receive topical Mitomycin after endoscopic dilatation of caustic esophageal stricture.For patients in this group, esophageal dilatation with Savarry Gillard dilatators or through the scope (TTS) balloons will be done. after esophageal dilatation, 5 cc of mitomycin C at a concentration of 0.4 mg per cc(from KOREA UNITED

FARM INC.) is applied topically through endoscopy at the site of mucosal rupture. The number of endoscopy and dilatation sessions is five times at intervals of at least two weeks.

Category

Treatment - Drugs

2

Description

Control group:Patients in the control group, like patients in the intervention group, undergo endoscopy and endoscopic esophageal dilatation at intervals of at least two weeks for five sessions, but they will not receive topical mitomycin after esophageal dilatation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Akbar's Pediatric Hospital

Full name of responsible person
Fatemeh Basirinezhad

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Akbar hospital,Shahid Kaveh 14 Alley, Shahid Kaveh Blvd. Mashhahd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

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Grant name

Grant code / Reference number
981304

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
Fatemeh Basirinezhad

Position
Sub-specialty Assistant

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Hamid Reza Kianifar

Position
full professor

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Subspecialist

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Pediatric gastroenterology and Liver disease

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Person responsible for updating data

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Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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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
There is no further information.

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

Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available