

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 randomization.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 envelope 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)

Phone

+98 51 3605 7487

Email address

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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, Ghoreshishi Building, Daneshgah street, Mashhad, Iran

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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 dilators 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. Mashhad

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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

Latest degree

Subspecialist

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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