

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the Effect of 4% Topical Sucralfate in Peristomal Wound Reaction prevention in Children with Endoscopic Percutaneous Gastrostomy in comparison with control group

Protocol summary

Study aim

Determination of the effect of topical sucralfate 5% on prevention of peristomal reaction in children with endoscopic percutaneous gastrostomy compared with control group

Design

A randomized controlled clinical trial with a parallel, single-blind, so that eligible individuals were randomly assigned to each of the case and control groups in a randomized block design with volume 4.

Settings and conduct

This randomized clinical trial will be performed on patients undergoing percutaneous endoscopic gastrostomy at Imam Hossein Hospital in Isfahan. Sucralfate gel 4% will be used immediately after gastrostomy and then 4 times daily (every 6 hours) as a thin-layer overlay covering at least one gram of skin around the ostomy site for 2 months. The researcher does not know which patients receive topical sucralfate and which patients do not.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient is able to do endoscopy. There are not any untreated coagulopathy, peritonitis, ascites, bowel obstruction, gastric mucosal abnormalities, previous abdominal surgery at the time of gastrostomy. Patients are not eligible for anti-inflammatory or antibiotic treatment. Exclusion criteria: Severe or advanced pyoderma gangrenosum Abdominal wall infection Need to antibiotics or anti-inflammatory medications for any non-reactive periosteal cause Gastrostomy should be removed for any reason The drug is not be used in sufficient quantity and duration for any reason Unwillingness to continue the study by parents or the patient

Intervention groups

Sucralfate gel 4% will be used immediately after gastrostomy and then 4 times daily (every 6 hours) as a

thin-layer overlay covering at least one gram of skin around the ostomy site for 2 months. In the control group no drug is used and rinsing with normal saline will be done.

Main outcome variables

Peristomal Wound Reaction, Peristomal infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131119015455N3**

Registration date: **2019-12-25, 1398/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-25, 1398/10/04**

Update count: **0**

Registration date

2019-12-25, 1398/10/04

Registrant information

Name

Bahareh Abtahi-Naeini

Name of organization / entity

Skin Diseases and leishmaniasis research Center, Isfahan University of Medical Sciences, Isfahan, Ir

Country

Iran (Islamic Republic of)

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+98 31 1264 2901

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-29, 1398/07/07
Expected recruitment end date
 2021-09-29, 1400/07/07
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Evaluation of the Effect of 4% Topical Sucralfate in Peristomal Wound Reaction prevention in Children with Endoscopic Percutaneous Gastrostomy in comparison with control group

Public title
 Effect of Topical Sucralfate in Peristomal Wound Reaction prevention in Children

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patient is able to do endoscopy. There are not any untreated coagulopathy, peritonitis, ascites, bowel obstruction, gastric mucosal abnormalities, previous abdominal surgery at the time of gastrostomy. Patients are not eligible for anti-inflammatory or antibiotic treatment.
Exclusion criteria:
 Severe or advanced pyoderma gangrenosum Abdominal wall infection Need to antibiotics or anti-inflammatory medications for any non-reactive periosteal cause Gastrostomy should be removed for any reason The drug is not be used in sufficient quantity and duration for any reason Unwillingness to continue the study by parents or the patient

Age
 From **1 month** old to **18 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Investigator

Sample size
 Target sample size: **44**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Eligible individuals were randomly assigned to each of the case and control groups in a randomized block design with volume 4.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 The researcher does not know which patients receive topical sucralfate and which patients do not.

Placebo
 Not used

Assignment

Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Technology Deputy of Isfahan University of Medical Sciences

Street address

Research and Technology Deputy of Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-06-12, 1398/03/22

Ethics committee reference number

IR.MUI.MED.REC.1398.297

Health conditions studied

1

Description of health condition studied

Peristomal Wound Reaction due to Endoscopic Percutaneous Gastrostomy

ICD-10 code

Z93.1

ICD-10 code description

Gastrostomy status

Primary outcomes

1

Description

Peristomal Wound Reaction

Timepoint

Evaluation of Peristomal Wound Reaction before intervention and then one week after using the topical sucralfate and then monthly for five months.

Method of measurement

Clinical evaluation, Index of Peristomal Wound Reaction grading, Index of Total Daily Peristomal Infection Score

Secondary outcomes

1

Description

Side effects of drug use

Timepoint

After drug use daily for 2 months and then monthly for up to 3 months

Method of measurement

Clinical evaluation

Intervention groups

1

Description

Intervention group: Sucralfate gel 4% (that it will be made in School of Pharmacy and Pharmaceutical Sciences of Isfahan University of Medical Sciences) will be used immediately after gastrostomy and then 4 times daily (every 6 hours) as a thin-layer overlay covering at least one gram of skin around the ostomy site for 2 months.

Category

Prevention

2

Description

Control group: In the control group no drug is used and rinsing with normal saline will be done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr. Mehrdad Memarzadeh

Street address

Imam Hossein Hospital, Imam Khomeini Avenue, Isfahan

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8195163381

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

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research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Atoosa Mehrannia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Hossein Saneian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Primary outcome data can be shared.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Descriptive analysis is allowed to report on data if available

From where data/document is obtainable

Bahareh Abtahi Skin Diseases and Leishmaniasis
Research Center, Isfahan, Iran Email:
bahareh.abtahi@med.mui.ac.ir

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

The request is discussed in the Center Committee and after approval, the data is submitted to the applicant over a period of approximately one month.

Comments