Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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 stydy 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)

Phone

+98 31 1264 2901

Email address

bahareh.abtahi@med.mui.ac.ir

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 stydy 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

Isfehan

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

City

Isfahan

Province

Isfehan

Postal code

8195163381

Phone

+98 31 3386 6266

Email

emamhossein_hospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

Street address

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

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 3061

Email

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

Street address

Imam Hossein Hospital, Imam Khomeini Avenue, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8195163381

Phone

+98 31 3386 6266

Email

atoosamehrannia@gmail.com

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

Street address
Imam Hossein Hospital, Imam Khomeini Avenue, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8195163381

Phone
+98 31 3386 6266

Email
saneian@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Bahareh Abtahi

Position
Assisstant Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
Skin Diseases and Leishmaniasis Research Center, Hazrat Sedighe Tahereh Complex, Khorram Avenue, Isfahan

City
Isfahan

Province
Isfehan

Postal code
7346181746

Phone
+98 31 3335 9090

Email
bahareh.abtahi@med.mui.ac.ir

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