

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effect of egg lotion on treatment of SRU

Protocol summary

Study aim

Effect of adding egg lotion to routine treatment of solitary rectal ulcer.

Design

After receiving patients' consent and confirmation of existence of solitary rectal ulcer, patients are randomly assigned to two groups of 30 people. The randomization method is that envelopes containing drugs are provided and numbered by an individual outside the study based on a random allocation table. Then these envelopes are handed to patients in turn.

Settings and conduct

This is a double-blinded clinical trial in which researcher and patient are unaware of the type of intervention and is carried out on 60 patients with solitary rectal ulcer in Ghaem Hospital of Mashhad. Participants are randomly divided into intervention and control groups. Both groups are advised to use fiber for soft stools. Outpatient treatment is done for 7 days. Patients are examined every two days during treatment. After completing the course of treatment, patients are followed up monthly for a period of three months. After the three-month period, recto-sigmoidoscopy is carried out for confirmation or rejection of complete SRU improvement.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with rectology who are confirmed to have solitary rectal ulcer through recto-sigmoidoscopy.

Intervention groups

Intervention group: In addition to sucralfate enema, anti solitary rectal ulcer egg lotion is prescribed. Control group: sucralfate enema is prescribed.

Main outcome variables

rate of improvement of solitary rectal ulcer, rate of hemorrhage improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140824018915N7**

Registration date: **2018-05-21, 1397/02/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-21, 1397/02/31**

Update count: **0**

Registration date

2018-05-21, 1397/02/31

Registrant information

Name

Mousalreza Hosseini

Name of organization / entity

Mashhad University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 80 1274 2513

Email address

hoseinimr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-12, 1396/11/23

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of egg lotion on treatment of SRU

Public title

Evaluation of the effect of egg lotion on treatment of solitary rectal ulcer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with rectology who are confirmed to have solitary rectal ulcer through recto-sigmoidoscopy

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple randomization method is that envelopes containing drugs are provided and numbered by an individual outside the study based on a random allocation table. Then these envelopes are handed to patients in turn.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blinded study in which researcher and patient are unaware of the type of intervention which means researcher and patient have no knowledge of the content of the envelope and treatment method.

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

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

345 - 91357

Approval date

2017-12-13, 1396/09/22

Ethics committee reference number

IR.MUMS.fm.REC.1396.442

Health conditions studied**1****Description of health condition studied**

Solitary rectal ulcer syndrome

ICD-10 code

K62.6

ICD-10 code description

Ulcer of anus and rectum

Primary outcomes**1****Description**

rate of improvement of solitary rectal ulcer

Timepoint

Patients are under treatment for 7 days. They are examined every two days during treatment period. After completing the course of treatment, patients are followed up monthly for three months. After the three month period, recto-sigmoidoscopy is carried out.

Method of measurement

use of recto-sigmoidoscopy for confirmation or rejection of complete improvement of the SRU

2**Description**

rate of hemorrhage improvement

Timepoint

Patients are under treatment for 7 days. They are examined every two days during treatment period. After completing the course of treatment, patients are followed up monthly for three months. After the three month period, recto-sigmoidoscopy is carried out.

Method of measurement

Clinical examination and recto-sigmoidoscopy

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In addition to sucralfate enema, anti solitary rectal ulcer egg lotion is prescribed.

Category

Treatment - Drugs

2**Description**

Control group: sucralfate enema is prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Dr Mousalreza Hoseini

Street address

Ahmad Abad Ave, Ghaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Email

hoseinimr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

345 - 91357

Phone

+98 51 3841 2081

Email

ramresearch@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

Fatemeh Dadellahi

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

Street address

Ahmad Abad Ave, Ghaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2742

Email

Dadelahif901@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mousalreza Hoseini

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Ahmad Abad Ave, Ghaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2742

Email

hoseinimr@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mousalreza Hoseini

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Ahmad Abad Ave, Ghaem hospital

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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

In case organizations ask for the data of participants, the data will become accessible for them.

When the data will become available and for how long

The data can be accessible for specific organization request 6 month after the article is published.

To whom data/document is available

All academic institutes and non-academic industrial institutes which are related to our studies will have access to our data after going through legal procedures.

Under which criteria data/document could be used

In case those people asking for data have the intention of optimizing the study an data and producing more results, access to data is allowed.

From where data/document is obtainable

Through sending an email to the corresponding author, data will be obtainable.

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

In case someone asks for data, he must first get in contact with the corresponding author for his identity to be fully verified. Then if university allows propagation of data, it will be accessible in 3 months.

Comments