

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of aloe vera gel on the healing of peristomal skin complications in patients with colostomy or ileostomy

Protocol summary

Summary

The aim of this clinical trial is to determine the effect of aloe vera gel on the healing of peristomal skin complications in patients with colostomy or ileostomy. The study population includes all patients with colostomy or ileostomy referred to colorectal clinics of Shiraz University of Medical Sciences and Milad Clinic. The study sample (60) will be selected by convenience sampling method and then will be divided into control and experimental groups by the random block method. Inclusion criteria includes having colostomy or ileostomy and peristomal skin complications (getting 2-15 score based on DET score scale) and lasting at least 6 weeks from last radiotherapy and not having auto immune diseases or immunodeficiency. Exclusion criteria includes the use of another product on the peristomal skin or tumor relapse in the area or worsening the condition of peristomal skin during the intervention. In the experimental group, the intervention includes using aloe vera gel on peristomal skin after each bag changing. In the control group, the intervention is the common methods using in each clinic. The duration of intervention is six weeks and telephone follow up is done every 3 days. The data will be collected by DET score tools. The severity score of peristomal skin complications will be determined and recorded before intervention , and after 3 and 6 weeks of starting intervention .The expected impact is the decrease of DET score and healing peristomal skin complications after intervention .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061534556N1**

Registration date: **2017-06-27, 1396/04/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-27, 1396/04/06

Registrant information

Name

Negar Ejtemaei

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

stud2440060348@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2017-06-26, 1396/04/05

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aloe vera gel on the healing of peristomal skin complications in patients with colostomy or ileostomy

Public title

The effect of aloe vera gel on the treatment of peristomal skin complications

Purpose

Treatment

Inclusion/Exclusion criteria

having willingness to enter the study; having colostomy or ileostomy with peristomal skin complications (getting 2-15 score based on DET score scale); being at least 18 years old; not having auto immune diseases or immunodeficiency; lasting at least 6 weeks from last radiotherapy; not having sensitivity to aloe vera gel:Inclusion criteria. not having willingness to enter the study; tumor relapse in the area; using another product on the peristomal skin; worsening the condition of peristomal skin during the intervention:Exclusion criteria.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central Building Shiraz University of Medical Sciences;Zand Ave ;Shiraz.

City

Shiraz

Postal code

Approval date

2017-02-18, 1395/11/30

Ethics committee reference number

IR.SUMS.REC.1395.195

Health conditions studied

1

Description of health condition studied

peristomal skin complications

ICD-10 code

k91.4

ICD-10 code description

colostomy and enterostomy malfunction

Primary outcomes

1

Description

peristomal skin complications

Timepoint

before intervention, 3 weeks after starting intervention, 6 weeks after starting intervention

Method of measurement

DET score tools

Secondary outcomes

empty

Intervention groups

1

Description

Intervention includes using aloe vera gel on peristomal skin after each bag changing.Purity percent of the gel is 99.9%. The gel should cover the skin surface with 1 mm thickness and use for 6 weeks:Intervention group

Category

Treatment - Drugs

2

Description

Intervention is the common methods using in each clinic:control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza clinic

Full name of responsible person

Negar Ejtemaei

Street address

Imam Reza clinic; Namazi Square; Shiraz; Iran

City

Shiraz

2

Recruitment center

Name of recruitment center

Milad clinic

Full name of responsible person

Negar Ejtemaei

Street address

Milad clinic; West Qodosi Street; Shiraz; Iran

City

Shiraz

negarejtemaei@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mahboube Magharei

Position

Graduate

Other areas of specialty/work**Street address**

Department of Nursing, School of Nursing and Midwifery (R), Shiraz University of Medical Sciences, Shiraz, Iran

City

Shiraz

Postal code**Phone**

+98 71 3647 4254

Fax**Email**

negarejtemaei@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Negar Ejtemaei

Street address

Shiraz University of Medical Sciences;Zand Ave;Shiraz;Iran

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Negar Ejtemaei

Position

Nursing Graduate Student

Other areas of specialty/work**Street address**

Shiraz University of Medical Sciences;zand ave; Shiraz;Iran

City

Shiraz

Postal code**Phone**

+98 71 3647 4254

Fax**Email****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Negar Ejtemaei

Position

Nursing Graduate Student

Other areas of specialty/work**Street address**

Shiraz University of Medical Sciences;zand ave; Shiraz;Iran

City

Shiraz

Postal code**Phone**

+98 71 3647 4254

Fax**Email**

negarejtemaei@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report**

empty
Analytic Code
empty

Data Dictionary
empty