Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Negar Ejtemaei
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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 peristamal 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

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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Negar Ejtemaei
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Shiraz University of Medical Sciences;Zand Ave;Shiraz;Iran
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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
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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