Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Chamomile Extract on Prevention of Stoma Dermal Complications

Protocol summary

Study aim
Determination of the Effect of Chamomile Extract on Prevention of Skin Complications ostomy
Design
A clinical trial with a control group, with a parallel group, one blind, randomized
Settings and conduct
The study in the Korosh Clinic of Isfahan is done on ostomy patients. In order to blind patients, containers containing an extract and placebo are same
Participants/Inclusion and exclusion criteria
The study population included all patients with colostomy and Ileostomy who had been operated less than 2 months ago
Intervention groups
Rubbing chamomile extract on the skin around the stoma in the intervention group and rubbing distilled water in the control group
Main outcome variables
Determining the frequency of ulcers in the skin around the stoma in the test and control group؛ Determine the frequency of types of secretions in the skin around the osteomy in the test and control group ؛ Determine the frequency of skin color changes around the osteomy in the test and control group

General information

Reason for update
Acronym
ECOS
IRCT registration information
IRCT registration number: **IRCT20180802040674N1**
Registration date: **2018-09-22, 1397/06/31**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-22, 1397/06/31**
Update count: **0**

Registration date
2018-09-22, 1397/06/31

Registrant information
Name
Abbas Abedi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3264 2781
Email address
ravabet@ems.mui.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-15, 1397/06/24
Expected recruitment end date
2018-11-15, 1397/08/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Chamomile Extract on Prevention of Stoma Dermal Complications

Public title
The Effect of Chamomile Extract on Stomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with colostomy or ileostomy who had surgery for less than 2 months save Ostmy for the patient at least 2 months If chemotherapy or radiation therapy has

been at least 7 weeks since the last treatment period
Exclusion criteria:
skin Complications include: wound, inflammation and secretion of skin around the ostomy History of chemotherapy or radiation therapy in the last 50 days History of skin diseases including allergic disorders, skin allergy, Psoriasis, Candidiasis

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients referred to the clinic will be divided into two intervention and control groups with the random allocation software.

Blinding (investigator's opinion)
Single blinded

Blinding description
The container containing essential oil and placebo will be the same for both groups of intervention and control And ET nurse will not be informed of the type of patients. .

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
3th of Qotb –e Ravandi Blvd., Kashan., IRAN

City
Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2018-07-01, 1397/04/10

Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1397.019

Health conditions studied

1

Description of health condition studied
ostomy skin complications

ICD-10 code
L23.1

ICD-10 code description
Allergic contact dermatitis due to adhesives

Primary outcomes

1

Description
Complications of the skin around the stomy

Timepoint
Skin complications around the stoma will be observe before the study and 7, 14, 21, and 28 days after the study

Method of measurement
Using a researcher-made tool

Secondary outcomes

1

Description
Skin Complications

Timepoint
will be observe before the study and 7, 14, 21, and 28 days after the study

Method of measurement
The tool is a researcher made

Intervention groups

1

Description
Intervention group: Use Chamomile extract that made in barij co. on the skin around the stomy after each change ostomy bag for one month.

Category
Prevention

2

Description
Control group: In this group, distilled water is used as a placebo in essential oil containers.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kourosh Specialized Clinic of Health and Diabetes

Full name of responsible person
Dr. Hosseini Muhammad

Street address
Sheikh Mofid st.

City
Isfahan

Province
Isfehan

Postal code
8154658781

Phone
+98 31 3664 3445

Fax
+98 31 3664 3445

Email
kouroshclinik@yahoo.com

Web page address
http://www.kouroshclinic.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Dr. Hamidi Gholamali

Street address
3th of Qotb –e Ravandi Blvd., Kashan., IRAN

City
Isfahan

Province
Isfehan

Postal code
8715988141

Phone
+98 31 5554 2999

Fax
+98 31 5557 5057

Email
hamidi_gh@kaums.ac.ir

Web page address
http://research.kaums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Kashan 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
Abedi Abbas

Position
Paramedic

Latest degree
Bachelor

Other areas of specialty/work
Emergency Medical Services

Street address
Hezar Jarib st, Isfahan University Of Medical Sciences, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
۷۳۴۶۱۸۱۷۴۶

Phone
+98 31 3273 1060

Email
abbasabedi2006@yahoo.com

Web page address
https://mui.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Abedi Abbas

Position
Paramedic

Latest degree
Bachelor

Other areas of specialty/work
Emergency Medical Services

Street address
Isfahan Medical University, Hezar Jarib st.Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
۷۳۴۶۱۸۱۷۴۶

Phone
+98 31 3273 1060

Email
abbasabedi2006@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Abedi Abbas

Position
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City
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Province
Isfehan

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۷۳۴۶۱۸۱۷۴۶

Phone
+98 31 3273 1060

Email
abbasabedi2006@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available