

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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**

Isfahan

**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.

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kouroshclinic@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**

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**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

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Isfahan

**Province**

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۷۳۴۶۱۸۱۷۴۶

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#### Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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## 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