

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessment of the Effect of Local Scrophularia Striata Solotion on Healing of Peristomal Wound in Patients Referring to Tehran Ostomi Assosiation

#### Protocol summary

##### Study aim

Determining the effect of local solution of Scrophularia Striata on the rate of wound healing around the ostomy in patients referred to the ostomy association

##### Design

The clinical trial has a control group and an intervention group in parallel, without blinding, the sampling method is done in two stages. In the first stage, the samples are studied by the available method. In the second stage, the samples will be randomly assigned to two groups. Randomization will be done using Excel software and the rand command

##### Settings and conduct

Sampling will be done in the Iranian Ostomy Association. After sampling and randomization, first, the information form related to demographic and clinical characteristics was collected, and then in both control and test groups, the skin around the ostomy was first checked using the ostomy examination tool. The intervention should be carried out for 14 days

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Not using drugs that affect the wound, such as corticosteroids, anti-inflammatory steroids  
Absence of infection symptoms such as fever, discharge  
No need for surgery and wound healing  
Not suffering from skin diseases such as lupus, psoriasis, dermatitis  
No radiotherapy or chemotherapy in the last 4 months  
The age of the participants is over 18 years  
Insensitivity to the Scrophularia Striata plant  
exclusioncriteria : Need for emergency surgery

##### Intervention groups

The patients of the intervention group are taught to apply the local solution of thirst-quenching plant at a specified time using an applicator to the skin around the stoma and repeat this every day for 14 consecutive days. And in the control group, he receives the usual training of the ostomy center (use of chamomile ointment).

##### Main outcome variables

intensity of color change, amount of tissue damage to

the dermis and epidermis, tissue overgrowth (granulation)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230510058145N1**

Registration date: **2023-06-06, 1402/03/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-06-06, 1402/03/16**

Update count: **0**

##### Registration date

2023-06-06, 1402/03/16

##### Registrant information

##### Name

kimia miri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8865 5366

##### Email address

kimiamiri@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-22, 1402/03/01

##### Expected recruitment end date

2023-08-23, 1402/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Assessment of the Effect of Local Scrophularia Striata Solotion on Healing of Peristomal Wound in Patients Referring to Tehran Ostomi Assosiation

## Public title

Assessment of the Effect of Local Scrophularia Striata Solotion on Healing of Peristomal Wound

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Not using drugs that affect the wound, such as corticosteroids, anti-inflammatory steroids Absence of infection symptoms such as fever, discharge No need for surgery and wound healing Not suffering from skin diseases such as lupus, psoriasis, dermatitis Insensitivity to the Scrophularia Striata plant No radiotherapy or chemotherapy in the last 4 months

### Exclusion criteria:

The use of drugs effective on wounds such as corticosteroids, anti-inflammatory steroids Having symptoms of infection such as fever, discharge The need for surgery and wound healing Suffering from skin diseases such as lupus, psoriasis, dermatitis Allergy to the Scrophularia Striata plant History of radiotherapy or chemotherapy in the last 4 months

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The sampling method takes place in two stages. In the first stage, the samples are entered into the study in the accessible(continuous) method. In the second stage, the samples will be randomly assigned to two control and test groups. Randomization will be done using Excel software and the rand command.

## 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 in research of School of pharmacy, nursing & midwifery , Shahid Beheshti Universi

##### Street address

School of Nursing Midwifery, Shahid Beheshti University, Wali Asr St., Niayesh Intersection, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2023-04-25, 1402/02/05

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.008

## 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

on Healing of Peristomal Wound Using the ostomy skin tool

#### Timepoint

The skin around the stoma will be examined on days 3, 7, 14 and 21 of treatment

#### Method of measurement

ostomy skin tool

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients in the intervention group are taught that after cleaning the skin around the stoma with water, apply the local solution of Local Scrophularia Striata provided to them at a specified time using an applicator on the skin around the stoma, and this Repeat the work every day for 14 consecutive days. During the intervention, the wound around the stoma is evaluated

by the tool for examining the skin around the stoma on the 3rd and 21st days, the duration of the treatment is evaluated by visiting the patient in person, and on the 7th and 14th, the skin around the stoma is evaluated virtually by the photos sent by the patients of the skin around the stoma. An ostomy will be made. It should be noted that during the study, patients will be continuously taught through virtual communication channels such as WhatsApp. (The preparation of the solution is that theLocal Scrophularia Striata collected in dry shade and after the plant extract is powdered with hydroalcoholic solvent (70%) is prepared by the maceration method for 72 hours. Then, the solution is passed through a strainer and If necessary, the solvent will be removed, the obtained solution will be poured into sterile containers and will be provided to the patient for topical use.

#### Category

Treatment - Drugs

## 2

#### Description

Control group: Patients in the control group are taught to apply the chamomile ointment used in the ostomy center, which is provided to them, to the skin around the ostomy at a specified time after cleaning the skin around the ostomy with water. Repeat every day for 14 consecutive days. During the intervention, the wound around the stoma is evaluated by the tool for examining the skin around the stoma on the 3rd and 21st days, the duration of the treatment is evaluated by visiting the patient in person, and on the 7th and 14th, the skin around the stoma is evaluated virtually by the photos sent by the patients of the skin around the stoma. An ostomy will be made. It should be noted that during the study, patients will be continuously taught through virtual communication channels such as WhatsApp.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iran Ostomy Society

##### Full name of responsible person

Hadi Manafi

##### Street address

No. 6, Shahid Ismailzade Alishah Alley (Maghan),  
Shahid Mirzaei Bei Ghosh St. (4th), Fatemi St

##### City

Tehran

##### Province

Tehran

##### Postal code

1415755991

##### Phone

+98 21 8896 9602

##### Fax

+98 21 8896 9602

#### Email

info@iranostomy.com

#### Web page address

https://iranostomy.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Hossein Vahidi

##### Street address

School of Nursing Midwifery, Shahid Beheshti  
University, Wali Asr St., Niayesh Intersection, Tehran

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##### Province

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##### Postal code

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##### Phone

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##### Fax

+98 21 8865 5366

##### Email

sbmuf@sbmu.ac.ir

##### Web page address

https://nm.sbm.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

kimia Miri

##### Position

MSc Medical Surgical Nursing

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery  
**Street address**  
School of Nursing Midwifery, Shahid Beheshti  
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**Email**  
kimiamiri@sbmu.ac.ir  
**Web page address**  
<https://nm.sbmu.ac.ir>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Mitra Zandi  
**Position**  
Post Doctorate in Nursing, Member of Faculty of  
Shahid Beheshti University of Medical Sciences  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
School of Nursing Midwifery, Shahid Beheshti  
University, Wali Asr St., Niayesh Intersection, Tehran  
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mitra.zandi@yahoo.com  
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<https://nm.sbmu.ac.ir>

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Kimia Miri  
**Position**  
MSc Medical Surgical Nursing  
**Latest degree**

Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
School of Nursing Midwifery, Shahid Beheshti  
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kimiamiri@sbmu.ac.ir  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

### Title and more details about the data/document

Results and data that are not ethically prohibited will be made available

### When the data will become available and for how long

6 months after printing the results

### To whom data/document is available

Person responsible for scientific inquiries & Person responsible for general inquiries

### Under which criteria data/document could be used

Checking for non-contradiction with the ethical principles of research and preserving the effect of ownership

### From where data/document is obtainable

Person responsible for scientific inquiries & Person responsible for general inquiries

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

Checking for non-contradiction with the ethical principles of research and preserving the effect of ownership

### Comments

