

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of Marsh Mallow Ointment on Incontinence-associated dermatitis(IAD) in the elderly

Protocol summary

Study aim

The effect of Marsh Mallow Ointment on Incontinence-associated dermatitis (IAD)

Design

This study is a randomized, double-blind, controlled clinical trial. 88 patients will be assigned randomly in two groups of drug and placebo.

Settings and conduct

The research will be carried out in the hospital wards of Shaheed Mostafa Khomeini Hospital. Before implementing the intervention; the researcher will complete the demographic information form and Incontinence-associated dermatitis and its severity (IADS) instrument. 88 patients will be assigned randomly in two groups of drug and placebo. In the drug and Placebo group, 1% Marsh Mallow Ointment and Vaseline will be used topically twice a day for seven days, respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria include Aged 60 years and up; the presence of Incontinence-associated dermatitis; having informed consent; the probability of hospitalization for 7 days; Exclusion criteria include: Having sensitivity to drug; having any kind of infection, bruising, scratching or skin lesions at the treatment site

Intervention groups

Drug Group: In this group, 1% Marsh Mallow Ointment will be used topically twice a day for seven days. Placebo group: In this group, vaseline (placebo) will be used topically twice a day for seven days.

Main outcome variables

incontinence associated Dermatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181121041711N1**

Registration date: **2019-05-27, 1398/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-27, 1398/03/06**

Update count: **0**

Registration date

2019-05-27, 1398/03/06

Registrant information

Name

Zohreh Ghadiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5592 4860

Email address

ghadiri2835@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Marsh Mallow Ointment on Incontinence-associated dermatitis(IAD) in the elderly

Public title

Effect of Marsh Mallow Ointment on Incontinence associated dermatitis(IAD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 60 years and up
The presence of Incontinence - associated dermatitis
Having informed consent
The probability of hospitalization for 7 days

Exclusion criteria:

Having sensitivity to drug
Having any kind of infection, bruising, scratching or skin lesions at the treatment site

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Random allocation to drug and placebo groups
Block randomization is performed using 4 blocks, including 2 drugs and 2 placebos. Accordingly, 22 blocks are allocated to patients. In each block, there are two people in group A and two in group B.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medication and placebo are encoded in similar containers. Participant, Clinician, Researcher, and outcome evaluator are not aware of the contents of the drug or placebo containers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahed University

Street address

Shahed University, Tehran-Qom Express Way,
Opposite Imam Khomeini's Shrine

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-10-29, 1397/08/07

Ethics committee reference number

IR.SHAHED.REC.1397.055

Health conditions studied

1

Description of health condition studied

Incontinence-associated dermatitis

ICD-10 code

L24

ICD-10 code description

Irritant contact dermatitis

Primary outcomes

1

Description

Incontinence-associated dermatitis

Timepoint

Measurement of the dermatitis in the beginning of the study (before starting the intervention) and from day 1-7 after starting taking Marsh Mallow.

Method of measurement

The Incontinence Associated Dermatitis And Its Severity Instrument

Secondary outcomes

1

Description

Any observed adverse event

Timepoint

during treatment course

Method of measurement

Side effects check form

Intervention groups

1

Description

Drug group: Patients in this group used Marshmallow ointment extracted with ethanol and 1% concentration, used topically and in a thin layer, twice a day for seven days.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group use vaseline

ointment (placebo) topically in the form of a thin layer twice a day for seven days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa Khomeini hospital

Full name of responsible person

Zohreh Ghadiri

Street address

Italya Ave, Felestin Squer, Mostafa Khomeini hospital

City

Tehran

Province

Tehran

Postal code

1416643491

Phone

+98 21 8896 6131

Email

mkht@shahed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Zahra Kiasalari

Street address

Shahed University, Tehran-Qom Express Way, Opposite Imam Khomeini's Shrine, 3319118651, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 5106

Fax

+98 21 5121 5107

Email

kiasalari@shahed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Zohreh Ghadiri

Position

Student of Master of Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Department of Nursing, Shahed University, Tehran-Qom Express Way, Opposite Imam Khomeini's Shrine, 3319118651, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 2146

Email

ghadiri2835@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mohammad Reza Heidari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Department of Nursing, Shahed University, Tehran-Qom Express Way, Opposite Imam Khomeini's Shrine, 3319118651, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 2146

Email

mheidari@shahed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Zohreh Ghadiri

Position

Student of Master of Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Department of Nursing, Shahed University, Tehran-
Qom Express Way, Opposite Imam Khomeini's Shrine,
3319118651, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 2146

Email

ghadiri2835@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