Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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Iran (Islamic Republic of)
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+98 21 5592 4860
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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 Asociated 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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Person responsible for scientific inquiries

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Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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