Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of gel containing pot marigoid (Calendula officinalis L.) and leaf Garden balsam(Lawsonia inermis) in the treatment of bed sores in patients in the intensive care ward of the Shahrekord Educational Hospital

Protocol summary

Study aim
Evaluation of the effect of gel containing Pot marigold (Calendula officinalis L.) and leaf Garden balsam (Lawsonia inermis) in the treatment of bed sores in patients in an intensive care ward of Shahrekord Educational Hospital

Design
A clinical trial with a control group, parallel groups, double-blind, randomized, phase 3 on 40 patients. RA software was used for randomization and blocking was used to match the groups.

Settings and conduct
Patients are selected from the hospitalized patients in the ICU ward of Hajar Hospital in Shahrekord according to the mentioned including and excluding criteria. This study will be conducted as a double-blind controlled clinical trial on patients with 1st and 2nd-degree bed sores. Eligible people who did not meet the exclusion criteria including underlying diseases, drug use, and sensitivity to the compounds used in this project, received the herbal gel and placebo gel. They are randomly divided into two groups. Both topical compounds are prepared in the same size and color packaging with the consultation and cooperation of the pharmacy specialist. In this study, the patients, the outcome assessor, and the analyzer are blinded.

Participants/Inclusion and exclusion criteria
Inclusion: Bed sore (Class 1-3) The satisfaction of the patient Exclusion: Suffering from chronic skin diseases, Discharge or transfer the patient to other medical centers during the study

Intervention groups
Intervention group: gel containing Pot marigold and leaf Garden balsam Control group: Placebo gel

Main outcome variables
Independent: Gel containing Pot marigolds and leaf Garden balsam Dependent: Bed-sore

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240707062349N1**
Registration date: **2024-08-15, 1403/05/25**
Registration timing: **prospective**

Last update: **2024-08-15, 1403/05/25**
Update count: **0**

Registration date
2024-08-15, 1403/05/25

Registrant information
Name
Lotfolah Afzali
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3333 5654
Email address
afzali@skums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-08-31, 1403/06/10
Expected recruitment end date
2024-10-31, 1403/08/10
Actual recruitment start date
2024-08-31, 1403/06/10

Actual recruitment end date
2024-10-31, 1403/08/10
Trial completion date
2024-11-01, 1403/08/11

Scientific title
Evaluation of the effect of gel containing pot marigoid (Calendula officinalis L.) and leaf Garden balsam(Lawsonia inermis) in the treatment of bed sores in patients in the intensive care ward of the Shahrekord Educational Hospital

Public title
Avaluation of the effect of gel containing pot marigoid (Calendula officinalis L.) and leaf Garden balsam(Lawsonia inermis) in the treatment of bed sores in patients in the intensive care ward of Shahrekord Educational Hospital
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
bed sores (class 1 - 3) The satisfaction of the patients
Exclusion criteria:
Suffering from chronic skin disease Discharge or transfer the patient to other medical centers during the study Allergies and skin, food and drug sensitivity
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals were entered into these groups randomly. Samples are grouped using RA software. The homogenization of the studied groups was based on the following variables: sex, age, type of wound, severity, and wound area.
Blinding (investigator's opinion)
Double blinded
Blinding description
Eligible participants who did not meet the exclusion criteria, such as underlying diseases, drug usage, and sensitivity to the compounds used in this project, were randomly assigned to either the gel containing pot marigold (Calendula officinalis L.) and leaf of Garden balsam (Lawsonia inermis), or the placebo gel group. Both topical compounds were prepared in the same size and color with the consultation and cooperation of a pharmacy specialist. The patients and the doctors will not know the type of medicine, and after the completion of the treatment plan, the identity of the medications will be revealed. This study will be conducted as a double-blind study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
88741
Approval date
2024-05-29, 1403/03/09
Ethics committee reference number
IR.SKUMS.MED.REC.1403.026

Health conditions studied

1

Description of health condition studied
Bedsore
ICD-10 code
A31.8
ICD-10 code description
Other mycobacterial infections

Primary outcomes

1

Description
Bedsore
Timepoint
Two months
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Gel containing Pot marigold (Calendula officinalis L.) and leaf Garden balsam (Lawsonia inermis). In this study, prepared gel from these two plants for one month is used topically daily twice . The score of the effect and characteristics of the wound is measured based on the PUSH standard criteria at the beginning of the study and at the end of each week. The data obtained of these four weeks' are compared.

Category
Diagnosis

2

Description
Control group: Placebo gel. In this study, prepared placebo gel from these two plants for one month is used topically daily twice. The score of the effect and characteristics of the wound is measured based on the PUSH standard criteria at the beginning of the study and at the end of each week. The data obtained of these four weeks' are compared.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Intensive care ward of Shahrekord Educational Hospital

Full name of responsible person
Lotfolah Afzali Borujeni

Street address
Shqhrekord University of Medicql Sciences, Kashani Blvd, Shahrekord

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
881571347

Phone
+98 913 382 6620

Email
afzali@skums.ac.ir

Web page address
https://researches.skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Mohammad Omrani

Street address
Shashrekord University of Medical Sciences, KashanI Blvd, Shahrekord,

City
Shqhrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8813833435

Phone
+98 38 3335 1031

Email
Omrani@skums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Lotfollah Afzali

Position
Academic Staff

Latest degree
Specialist

Other areas of specialty/work
General Surgery

Street address
Shahrekord Univ. of Med. Sci. Kashani Blvd, Shahrekord .

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8813833435

Phone
+98 38 3333 5654

Email
afzali@skums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Lotfollah Afzali Brojeni

Position
Academic staff

Latest degree
Specialist

Other areas of specialty/work
General Surgery

Street address
Shahrekord University of Medicql Sciences, Kashani Blvd, Shahrekord

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
881571347

Phone
+98 38 3335 1031

Email
afzali@skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Lotfolah Afzali Borujeni

Position
Academic Staff

Latest degree
Specialist

Other areas of specialty/work
General Surgery

Street address
Shahrekord Univ. of Med. Sci. Kashani Blvd, Shahrekord .

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8813833435

Phone
+98 38 3333 5654

Email
afzali@skums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No decision

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available