Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of Topical Royal Jelly on the Improvement of Bedsores in Hospitalized Patients in ICU

Protocol summary

Study aim

Evaluation of the effect of topical royal jelly on the healing process of pressure ulcers Evaluation of the effect of the combination of royal jelly and local honey in reducing pressure ulcer secretion, reducing the area of bed sores, reducing the score of the PUSH criterion, on the type of bedsores, on the healing time of bedsores.

Design

A clinical trial with a control group and an intervention group, a single blind, randomized on 60 patients, was used for randomization using the minimization method using Python.

Settings and conduct

In order to investigate the effectiveness of royal jelly on patients hospitalized in the ICU department of Baqiyatullah Hospital, the patients' bedsores are followed for 8 weeks based on PUSH score. For single blinding, only the doctors and nurses who are responsible for the implementation of the design, will know which group received royal jelly and which only received routine treatment. Patients and other doctors will not be aware of this process.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients hospitalized in the ICU, whose bedsores were examined by a wound specialist, were included in the study. Conditions of non-entry: patients with gangrene, osteomyelitis, severe sepsis, heavy smoking or alcohol consumption, liver failure, diabetes and taking drugs that may interfere with the wound healing process, lack of proper follow-up by patient, lack of consent to continue follow-up, lack of response to treatment, age under 18 years

Intervention groups

The control group will receive the usual treatment of bedsores in the hospital, and the combination of honey and royal jelly, also will be added to the intervention group.

Main outcome variables

Investigation of bed sore healing time, bed sore length and width, bed sore secretions and bed sore type for 8 weeks according to PUSH criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240727062554N1**
Registration date: **2024-08-17, 1403/05/27**
Registration timing: **prospective**

Last update: **2024-08-17, 1403/05/27**
Update count: **0**

Registration date

2024-08-17, 1403/05/27

Registrant information

Name

Reza Ghanbarpoor Dizbon

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8809 3854

Email address

ghanbarpoor@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-31, 1403/06/10

Expected recruitment end date

2024-12-30, 1403/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the Effect of Topical Royal Jelly on the Improvement of Bedsores in Hospitalized Patients in ICU

Public title
Effect of Topical Royal on the Improvement of Bedsores

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients hospitalized in ICU whose bedsores are studied by a wound expert.

Exclusion criteria:
Patients who have gangrene. Patients who have osteomyelitis. Patients who have severe sepsis. Patients who have heavy smoking or alcohol consumption. Patients who have liver failure. Patients who have diabetes. Taking drugs that may interfere with the wound healing process (glucocorticoid, immunosuppressive and cytotoxic drugs). Proper follow-up is not done by the patient. The patient does not consent to continue the follow-up. Failure to respond to treatment (wounds that do not respond to treatment after two months are included in this group). The age of the patient is under 18 years.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
-Randomization Method: Minimization Minimization is recognized as a valid approach for randomization, particularly in clinical trials where we want to ensure balance between treatment groups based on certain overlapping variables (such as age, gender, and severity of pressure ulcers). -Unit of Randomization: The unit of randomization in this study is a patient in the ICU who has developed a pressure ulcer. Each patient will be assigned to one of the treatment groups (receiving royal jelly) or the control group (receiving a placebo or standard care). -Randomization Tools: Statistical software in Python will be used. -Constructing the Randomization Sequence: The minimization method ensures that treatment groups are balanced concerning predetermined overlapping variables. Here's how to construct the randomization sequence: 1. Identify Overlapping Variables: Select the variables that are important for balance, such as age, gender, severity of pressure ulcers, or comorbid conditions. 2. Initiate Randomization: Start with the first patient and randomly assign them to one of the groups (treatment or control). 3. Minimization Algorithm: - For each subsequent patient, calculate the imbalance for both treatment groups based on the overlapping variables. - Assign the new patient to the treatment group that minimizes the overall imbalance across the overlapping variables. - This process can be repeated for each patient enrolled in the study. -Allocation Concealment: We will use Centralized Randomization: A third party will manage the randomization and allocation process. This person will not be involved in patient care or data collection.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, blinding was done only for the patients. This means that only the patients do not know what group they are in. During wound dressing, all patients or their companions will be told that the same dressings will be used for them. The wound specialists and the people responsible for the study will know which type of treatment the patient will receive

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Baqiyatallah Hospital

Street address
Baqiyatallah Hospital, Mollasadra Ave., Vanak Square

City
Tehran

Province
Tehran

Postal code
1435915371

Approval date
2024-06-29, 1403/04/09

Ethics committee reference number
IR.BMSU.BAQ.REC.1403.076

Health conditions studied

1

Description of health condition studied
Pressure ulcer(Bed sore)

ICD-10 code
L89

ICD-10 code description
Pressure ulcer

Primary outcomes

1

Description
Bed sore healing time
Timepoint
Twice a week for 8 weeks
Method of measurement
The amount of time it takes for the PUSH score to reach zero or one

2

Description
The length of the bed sore
Timepoint
Twice a week for 8 weeks
Method of measurement
Using a sterile ruler

3

Description
The width of the bed sore
Timepoint
Twice a week for 8 weeks
Method of measurement
Using a sterile ruler

4

Description
Bed sore secretions
Timepoint
Twice a week for 8 weeks
Method of measurement
It is classified based on the opinion of the expert and PUSH criteria

5

Description
Type of bed sore
Timepoint
Twice a week for 8 weeks
Method of measurement
Based on the expert's observation and opinion, the type of bed sore is classified

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: To 30 patients with bed sores in the ICU who were enrolled in the study by a wound expert, two days a week for 8 weeks, in addition to the routine treatment of bed sores (Tabasept spray, X-Plates gel, Urocel 10x10 and Tabaflex 10x10), the combination of royal jelly and honey will be given, and the patients will be followed up by the PUSH questionnaire during this period.
Category
Treatment - Other

2

Description
Control group: To 30 patients with bedsores in the ICU who were included in the study by a wound expert, two days a week for 8 weeks, routine treatment of bedsores (Tabasept spray, X-Plates gel, Eurocell 10x10 and Tabaflex 10x10) will be given and patients will be followed up by PUSH questionnaire during this period.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Mir Erfan Aribi
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Baqiyatallah Hospital, Mollasadra Ave., Vanak Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mir Erfan Aribi
Position
General Practitioner
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Non-identifiable personal information of participants in this study will be shared. Also, the protocol, results and statistical analysis of this study will be published in the relevant articles.
When the data will become available and for how long
The non-identifiable personal information of the participants will be available after the publication of the relevant articles.

To whom data/document is available

The non-identifiable personal information of the participants will be made available to other researchers at the scientific institutions after the investigation by the research team.

Under which criteria data/document could be used

Non-identifiable personal information of participants can only be used for research purposes.

From where data/document is obtainable

Non-identifiable personal information of the participants can be obtained by sending an email to Dr. Reza Ghanbarpoor (ghanbarpoor@bmsu.ac.ir) or Dr. Mirerfan Aribi (mirerfan.aribi@gmail.com).

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

Other researchers in scientific institutions can send their request to Dr. Reza Qanbarpour or Dr. Mirerfan Eribi. After consultation and approval of the research team, the results will be sent to them.

Comments