Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of honey on the treatment of patients with bedsores grade 1 and 2

Protocol summary

Study aim
Investigating the synergistic effect of honey on the healing of grade 1 and 2 bedsores in patients admitted to Ghaem Hospital in Mashhad

Design
Clinical trial with a control group, with parallel groups, single-blind, randomized, phase 2 on 40 patients. www.random.org was used for randomization.

Settings and conduct
In this clinical trial study, 40 patients with grade 1 and 2 bedsores are selected, who are hospitalized in Ghaem Hospital of Mashhad, and the wound area of these patients is taken on day 0. In 20 of these patients, unsterilized honey is used for dressing [9]. In addition, the presence of inflammatory factors such as CRP is also measured in the blood of these people, and the recovery process is checked and compared by means of a questionnaire. Number of blinds: one blind Blinding (subjects under study)

Participants/Inclusion and exclusion criteria
Inclusion criteria: People who have been confirmed with grade 1 and 2 bedsores and are hospitalized Criteria for not entering the study: People's lack of consent to participate in this study Age less than 18 years Allergy to honey Kidney failure patients Patients taking corticosteroids

Intervention groups
intervention group: In this group, unsterilized honey will be used. The intervention method is as follows: - Dressing: For each patient, 25 ml of unsterilized honey is placed on a dressing measuring 10 x 10 cm. - control group: In this group, in order to compare with the intervention group and to investigate the effects of honey, ordinary dressing will be used. The control method is as follows:

Main outcome variables
1. Characteristics of bedsores - Assessment and healing process of bedsores based on the PUSH (Pressure Ulcer Scale for Healing) checklist 2. Laboratory parameters - CBC diff - SGOT - SGPT - BUN - Cr - CRP - Alb - Total protein

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240627062264N1**
Registration date: **2024-07-09, 1403/04/19**
Registration timing: **prospective**

Last update: **2024-07-09, 1403/04/19**
Update count: **0**

Registration date
2024-07-09, 1403/04/19

Registrant information

Name
Forouzan Amerizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-20, 1403/06/30

Expected recruitment end date
2025-02-18, 1403/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of honey on the treatment of patients with bedsores grade 1 and 2

Public title
The effect of honey on bedsores

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People with bedsores grade 1 and 2 have been confirmed for these people Patients are hospitalized

Exclusion criteria:
People's lack of consent to participate in this study Age less than 18 years Allergy to honey Kidney failure patients Patients taking corticosteroids

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: To ensure a fair distribution of patients between control and treatment groups, we will use the stratified randomization method. In this method, patients are first classified into four groups based on age: 18-40 years, 40-60 years, 60-80 years, and over 80 years. Randomization Unit: The unit of randomization is individual (individual randomization), which means that each patient is individually assigned to one of the control or treatment groups. Randomization layers: Patients are classified into four age strata to ensure that the age distribution in both groups is balanced: 8-40 years, 40-60 years, 60-80 years, and over 80 years. Randomization Tool: [random.org] (https://www.random.org/) site is used to generate the random sequence. This site generates random numbers that will be used to assign patients to groups. How to make a random sequence First, patients are divided into four age groups based on age: the number of patients in each age group is determined to maintain the balance between age groups in both control and treatment groups. To determine the group of each patient (control or treatment), random.org is used. This site generates random numbers. The generated random numbers are assigned to the patients in order. For each random number, it is determined whether the patient will be assigned to the control or treatment group. This is done completely randomly to ensure a fair distribution of patients between the groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
allocation concealment: To conceal allocation and avoid bias, a blind method will be used: - Patients: Patients will not be informed of their group allocation (control or treatment) to reduce the effect of psychological bias. - The researcher analyzing the data: the researcher who analyzes the data will not be aware of the allocation of groups. This is done by coding the data in such a way that the identity of the groups is not known. This method ensures that the effect of bias in the randomization process and data analysis is minimized.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Azadi Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948959

Approval date
2024-03-09, 1402/12/19

Ethics committee reference number
IR.MUMS.REC.1403.007

Health conditions studied

1

Description of health condition studied
Bedsore

ICD-10 code
L89

ICD-10 code description
Pressure ulcer

Primary outcomes

1

Description
Our outcome is bed sore healing, which will be evaluated based on the PUSH questionnaire

Timepoint
Characteristics of bedsores - measurement at the

beginning of the study (day 0, before the start of the intervention) - measurement on days 3, 5, 8, 10, 12 - final measurement at the end of the study (day 15). Outcome 2: Laboratory parameters - measurement at the beginning of the study (day 0, before the start of the intervention) - final measurement at the end of the study (day 15)

Method of measurement

PUSH questionnaire

2

Description

Laboratory parameters - such as creatinine, C-reactive protein, alanine

Timepoint

Measurement at the beginning of the study (day 0, before the start of the intervention) - Final measurement at the end of the study (day 15)

Method of measurement

By taking blood and checking with valid laboratory kits and automatic devices

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Add 25 ml of honey to the size of 10x10 from the dressing used by bed sore patientsIn this group, unsterilized honey will be used in order to check the effectiveness of honey in healing bedsores. The intervention method is as follows: - Dressing: For each patient, 25 ml of unsterilized honey is placed on a dressing with dimensions of 10 x 10 cm. The dressings are changed carefully and the wounds are washed with normal saline.- Duration of intervention: dressing with honey is used for two weeks or until the wound heals. The process of healing or non-healing of wounds is checked using the PUSH (Pressure Ulcer Scale for Healing) questionnaire. Control group: In this group, in order to compare with the intervention group and to check the effects of honey, normal dressing will be used. The control method is as follows:- Dressing: For each patient, a normal dressing (vaseline gauze) without honey is used. The wounds are carefully washed with normal saline and the dressings are changed.- Duration of control: The normal dressing is used for two weeks or until the wound heals. The process of healing or non-healing of wounds is checked using the PUSH (Pressure Ulcer Scale for Healing) questionnaire. and will be evaluated. This questionnaire contains three categories of information:1. Depth and size of the wound2. The amount of wound secretion3. The type of tissue in the woundEach of these categories has specific subtypes that are graded based on them. Total scores are calculated from 0 (complete improvement) to 17 (most severe condition). Comparing scores over time shows whether the wound is improving or worsening.

Category

Diagnosis

2

Description

Control group: In this group, in order to compare with the intervention group and to investigate the effects of honey, normal dressing will be used. The control method is as follows:- Dressing: For each patient, a normal dressing (Vaseline gauze) without honey is used. The wounds are carefully washed with normal saline and the dressings are changed. - Duration of control: The usual dressing is used for two weeks or until the wound heals. The process of healing or non-healing of wounds is checked using the PUSH (Pressure Ulcer Scale for Healing) questionnaire. How to check the healing of wounds and the healing or non-healing of wounds in both groups will be investigated and evaluated using the PUSH (Pressure Ulcer Scale for Healing) questionnaire. This questionnaire contains three categories of information: 1 depth and size of the wound 2. The amount of wound secretion 3. The type of tissue in the wound, each of these categories has specific subtypes that are scored based on them. Total scores are calculated from 0 (complete improvement) to 17 (most severe condition). Comparing scores over time indicates whether the ulcer is improving or worsening:

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Forouzan Amerizadeh

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Sponsors / Funding sources

1

Sponsor

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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Forouzan Amerizadeh
Position
Researcher
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Person responsible for updating data

Contact
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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
1. Preservation of the privacy of the participants: In order to preserve the privacy of the participants in the study, it is necessary not to publish their personal data. 2. Data security: As a fundamental principle, it is vital to protect the sensitive data of participants from unauthorized

access and misuse. 3. Compliance with legal agreements: Research studies may have agreements with participants that prohibit the publication of individual data, and we must adhere to these agreements.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable