

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of bromelain capsule on stress, anxiety , depression in patients with diabetic foot ulcer

Protocol summary

Study aim

Determining the effect of bromelain capsule on stress, anxiety, depression in patients with diabetic foot ulcer

Design

Clinical trial with control group, single-blind, randomized with 44 patients in each group

Settings and conduct

Endocrinology and Metabolism Research Center., Tehran University of Medical Sciences, Tehran, North Iran, Tehran, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 60 years nformed consent
Mild or moderate score in DASS-21 pre-test
Exclusion criteria: The patient is taking drugs that interact with bromelain
Patients enrolled in other clinical trial studies
History of other wounds

Intervention groups

Bromelain capsules containing 200 mg of this substance (500 GDU) made by Permon Amin Company will be used orally twice a day (once in the morning before breakfast and once in the evening two hours after dinner) for 4 weeks.

Main outcome variables

Stress, anxiety, depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044148N2**

Registration date: **2022-04-26, 1401/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-26, 1401/02/06**

Update count: **0**

Registration date

2022-04-26, 1401/02/06

Registrant information

Name

Alireza Salmani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of bromelain capsule on stress, anxiety , depression in patients with diabetic foot ulcer

Public title

The effect of bromelain capsules on stress and depressive anxiety in diabetic foot ulcer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years Informed consent Mild or moderate score in DASS-21 pre-test

Exclusion criteria:

The patient is taking drugs that interact with bromelain
Patients enrolled in other clinical trial studies
History of

other wounds

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be assigned to two groups with a random permutation block design with four blocks. Thus, the letter A is considered for the intervention group and the letter B is considered for the control group. Then we write all the permutation combinations of the letters A and B, which are 6 different combinations, on 6 cards. Thus, BBAA, BABA, BAAB, ABAB, ABBA, AABBB, then one of the cards is selected by lottery. This means that the first and second persons are in the control group and the third and fourth persons are in the intervention group, and this will continue until the sample size quorum is reached. In order to prevent and reduce possible bias, the person who will perform a random sequence, check the criteria for entry and exit of participants and assign participants to the intervention and control group, is out of the research team.

Blinding (investigator's opinion)
Single blinded

Blinding description
On the other hand, in order to hide random allocation, it is sealed by non-transparent envelopes. In this way, a number of envelopes are prepared with aluminum wrappers and each of the random sequences created is recorded on a card and the cards are placed in the envelope in order. The sequence is numbered in the same way on the outer surface of the envelopes in order to maintain a random sequence. Finally, the envelopes are sealed and placed in a box. At the beginning of the registration of participants, according to the order of entry of eligible participants to study, one of the envelopes is opened in order and its assigned group. The participant will be revealed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

Street address
Tehran, Tohid Square, Dr. Mirkhani St. (Eastern Nusrat), School of Nursing and Midwifery

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2022-03-13, 1400/12/22

Ethics committee reference number
IR.TUMS.FNM.REC.1400.237

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer

ICD-10 code
E10.5

ICD-10 code description
Type 1 diabetes mellitus with circulatory complications

Primary outcomes

1

Description
Stress

Timepoint
Measurements before the study and 4 weeks after the start of the intervention

Method of measurement
Depression, Anxiety and Stress Questionnaire (DASS-21)

2

Description
Anxiety

Timepoint
Measurements before the study and 4 weeks after the start of the intervention

Method of measurement
Depression, Anxiety and Stress Questionnaire (DASS-21)

3

Description
Depression

Timepoint
Measurements before the study and 4 weeks after the start of the intervention

Method of measurement
Depression, Anxiety and Stress Questionnaire (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group Bromilin capsules containing 200 mg of this substance (500 GDU) made by Permon Amin Company twice daily (once in the morning before breakfast and once in the evening two hours after dinner) orally for 4 weeks after the start of the intervention they take.

Category

Treatment - Other

2

Description

Control group: The control group will not receive bromelain supplementation and will receive routine treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology & Metabolism Research Center

Full name of responsible person

Alireza Salmani

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NO 10, Jalal-AL-Ahmad St., Chmaran HWY., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Alireza Salmani

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Alireza Salmani

Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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