Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of Persian medicine Fasd on symptoms of patients with acne vulgaris

Protocol summary

Study aim
Determining the effect of Persian medicine phlebotomy (Fasd) on symptoms of patients with acne vulgaris

Design
Clinical trial with control group, with factorial groups, randomized, phase 2 on 60 patients. Without blinding, randomization will be done based on stratified patients into two men and women groups and determined blocks of 4 and Table of random numbers

Settings and conduct
The following steps are done in this study: Determining the severity of acne with the GAGS criteria at the beginning, at the end of months 1, 2, and 3, and measuring the quality of life based on the CADI questionnaire at the beginning and end of the study; Intervention by performing phlebotomy at the beginning and the end of the 2nd month, and taking 150 to 200 cc of blood from cephalic vein at every turn; Both groups receive classic acne treatment. Patients are selected from those who visit the Dermatology or Persian Medicine Clinic of Emam Reza Hospital, and blinding is done only on the analyzer.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People aged 16 to 25 with moderate to severe acne based on the GAGS index and willing to cooperate in the project Exclusion criteria: Other skin or systemic diseases, use of medications that can cause acne or anti-acne drugs in the past 3 months, history of allergy to the study drugs, iron deficiency anemia, emaciation, PCOS, general cold temperament, pregnancy or lactation

Intervention groups
Intervention by performing two rounds of Fasd and removing 150 to 200 cc of blood from the Cephalic vein in each round in addition to classical acne treatment (including 5% topical Benzoyl peroxide daily and 100 mg Doxycycline capsule twice a day orally); Control group receives only conventional acne treatment.

Main outcome variables
The severity of acne disease, Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231129060219N1**
Registration date: **2024-07-20, 1403/04/30**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-20, 1403/04/30**
Update count: **0**

Registration date
2024-07-20, 1403/04/30

Registrant information

Name
Mostafa Khosravi moghaddam

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-24, 1403/04/04

Expected recruitment end date
2025-12-25, 1404/10/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of Persian medicine Fasd on symptoms of patients with acne vulgaris

Public title
Investigating the effect of Fasd on acne

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People aged 16 to 25 years Moderate to severe acne based on GAGS criteria Not having general cold Mizaj (temperament) based on diagnosis of traditional Persian medicine expert and valid Mizaj questionnaire Willingness to cooperate in the project

Exclusion criteria:
Having other skin diseases other than acne Having serious liver and kidney diseases Patients with iron deficiency anemia Use of topical acne medicine in the last 2 weeks or any systemic anti-acne antibiotic treatment in the last 1 month or isotretinoin in the last 6 months Use of acne-causing drugs in the last month Chemical or laser peeling or UV treatment or photosensitizing drugs in the last month Drug sensitivity to tetracycline derivatives or benzoyl peroxide General cold temperament based on validated Mezaj questionnaire Body Mass Index lower than 19 Breastfeeding Pregnancy Patients diagnosed with Polycystic ovary syndrome Mentally retarded patients

Age
From **16 years** old to **25 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, the participants in the study are divided into two groups, male and female. Then six blocks of 4 will be created and a number will be assigned to each of the blocks: AABB(1)- ABAB(2)-ABBA(3)-BBAA(4)- BABA (5) - BAAB (6). Using the table of random numbers, a list will be selected from numbers 1 to 6 and randomization of the participants of both groups will be done based on the prepared list.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

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
Medical school، Mashhad University of Medical Sciences, Azadi Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2024-02-24, 1402/12/05

Ethics committee reference number
IR.MUMS.REC.1403.003

Health conditions studied

1

Description of health condition studied
Acne Vulgaris

ICD-10 code
L70.0

ICD-10 code description
Acne vulgaris

Primary outcomes

1

Description
Acne severity according to Global Acne Grading Score Index

Timepoint
At beginning of study and end of every month till 3 month

Method of measurement
Global Acne Grading Score Index

Secondary outcomes

1

Description
Quality of Life according Cardiff Disability Index

Timepoint
At beggining of Study and end of 3th month

Method of measurement
According Cardiff Acne Disability Index

Intervention groups

1

Description
Control group: Benzoyl Peroxide Gel 5% twice a day topically plus Doxycycline 100 mg capsule twice a day orally Plus Cephalic vein phelebotomy in the elbow crease area with an 18 Gauge Needle and drawing 150-200 cc blood at the beginning of the study and end of second month
Category
Treatment - Other

2

Description
Control group: Benzoyl Peroxide Gel 5% twice a day topically plus Doxycycline 100 mg capsule twice a day orally
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Mostafa Khosravi Moghaddam
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Reserch
Grant code / Reference number
4012335
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
Mostafa Khosravi Moghaddam
Position
PhD student
Latest degree
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Other areas of specialty/work
Traditional Medicine
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inquiries

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
After the end of the study, the results will be published in the form of an original paper in an international journal and will be available to other researchers. Access to raw data collected in this study will be possible after obtaining permission from the original researchers and the corresponding author. Using the data of this project to carry out research or publish a new article requires written permission from the person responsible for scientific inquiries in this research.

When the data will become available and for how long
Access starts from the time the article is published until one year later.

To whom data/document is available
Academic researchers by request from the corresponding author

Under which criteria data/document could be used
Access to raw data collected in this study will be possible after obtaining permission from the original researchers and the corresponding author. Using the data of this project to carry out research or publish a new article requires written permission from the person responsible for scientific inquiries in this research.

From where data/document is obtainable
Applicants can correspond with the responsible author via e-mail at derakhshanar@mums.ac.ir.

What processes are involved for a request to access data/document
An email containing the introduction of the requester and the reason for the request and the description of possible uses will be sent to the corresponding researcher. If the request is accepted by the corresponding researcher, the requested information will be sent to the applicant via email.

Comments