Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of the role of oral whey protein with Terminalia Chebula(an Iranian Medicine product) on mild to moderate skin lesion of psoriasis – A Triple-blind randomized controlled trial.

Protocol summary

Study aim

Evaluation of the role of oral whey protein with Terminalia Chebula (an Iranian Medicine product) on mild to moderate skin lesion of psoriasis – A Triple-blind randomized controlled trial

Design

A Triple-blind randomized controlled trial, with parallel groups and blinded outcome assessment, on 90 patients. Using Random Allocation Software or RAS, patients are divided into 2 groups: the intervention (whey protein with terminalia chebula) group and the control group (whey protein with starch).

Settings and conduct

90-patients diagnosed with psoriasis would be studied in the Center for Research and Training in Skin Disease and Leprosy. After applying the inclusion and exclusion criteria of the study and completing the informed consent form they are placed in one of the intervention or control groups using random blockade.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient diagnosed with mild to moderate controlled plaque psoriasis with less than 10% of skin involvement,that have age between 18 and 60. Exclusion criteria: History of the sever heart, and pulmonary and kidney disease, pregnancy and breastfeeding.

Intervention groups

Intervention group: The standard treatment + whey protein with terminalia chebula. Control group: Standard treatment + whey protein with placebo (starch).

Main outcome variables

Assessing the severity of the disease both before the treatment begins and at the end of the sixth and twelfth weeks, using PASI score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230618058508N1**
Registration date: **2023-07-02, 1402/04/11**
Registration timing: **prospective**

Last update: **2023-07-02, 1402/04/11**
Update count: **0**

Registration date

2023-07-02, 1402/04/11

Registrant information

Name

nasrin azhang

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4410 8623

Email address

nasrinazhang@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the role of oral whey protein with Terminalia Chebula(an Iranian Medicine product) on mild to moderate skin lesion of psoriasis – A Triple-blind randomized controlled trial.

Public title
Evaluation of the role of oral whey protein with Terminalia Chebula(an Iranian Medicine product) on mild to moderate skin lesion of psoriasis – A Triple-blind randomized controlled trial.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 60 Less than 10% of skin involvement Suffering from controlled plaque psoriasis (Unchanged damages in terms of severity and extent in the last 2 months) Not using psoralen in the last 28 days and not receiving UVB in the last 30 days No kidney disease or kidney stones Not being during pregnancy and breastfeeding Not participating in any study in the last month Consent to participate in the study

Exclusion criteria:
Suffering from other types of psoriasis, such as pustular, erythrodermic, palmoplantar, psoriatic arthritis Allergy to milk and other dairy product Suffering from kidney stones and kidney disease Using drugs aggravating psoriasis, such as beta-blockers, non-steroidal anti-inflammatory drugs, calcium channel blockers, interleukins, and lithium suffering from uncontrolled cardiovascular, respiratory, hematologic or urinary diseases

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by using random allocation software and creating a table of permutation blocks, which will have 15 blocks of six according to the size of sample and groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this project, the pharmaceutical consultant prepares medicine (whey protein and yellow Halila) and placebo (whey protein and starch) in the form of powder in cans of the same shape, weight, and color with specific codes. First, the demographic information is recorded on the form, and then the pocket containing medicine and placebo would be opened and randomly given to people in two groups. It should be noted that all these processes will be carried out by a pharmaceutical consultant and research assistant. In this study, the doctor, the patient and the statistician do not know the contents of the cans.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Institute of Pharmaceutical Sciences - Tehran University of Medical Sciences

Street address
13th floor,A bloc, Simay iran St., between Falamak St. and Zarafshan St.,

City
Tehran

Province
Tehran

Postal code
1467664961

Approval date
2023-06-11, 1402/03/21

Ethics committee reference number
IR.TUMS.TIPS.REC.1402.034

Health conditions studied

1

Description of health condition studied
Psoriasis

ICD-10 code
L40.0

ICD-10 code description
Psoriasis vulgaris

Primary outcomes

1

Description
Assessment of disease severity

Timepoint
Before starting the treatment and at the end of weeks 6 and 12

Method of measurement
Using PASI score

2

Description
Evaluation of the extent of the lesion
Timepoint
Before starting the treatment and at the end of weeks 6 and 12
Method of measurement
Using the BSA index

3

Description
Assessment of quality of life
Timepoint
It is evaluated before the start of the treatment and at the end of the 12th week.
Method of measurement
Using the DLQI index, which is taken from the patient in the form of a questionnaire

4

Description
Assessment of itching severity
Timepoint
It is evaluated before the start of the treatment and at the end of weeks 6 and 12
Method of measurement
Using the VAS index

5

Description
Investigation of possible gastrointestinal and skin complications
Timepoint
At the end of weeks 6 and 12
Method of measurement
Using the fifth version of Common Terminology for Adverse Event questionnaire (CTCAE)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They will receive the existing standard treatment of emollient ointment (20% glycerine based on Oserin) and tar shampoo + oral whey protein with terminalia chebula once a day. This group dissolves a full tablespoon (10 grams) of the drug in 1 glass of warm water and drinks it in the morning, about 30 minutes before breakfast. After drinking the medicine, the patient should walk 100 steps.
Category
Treatment - Drugs

2

Description
Control group: They will receive the existing standard treatment of emollient ointment (20% glycerine based on Oserin) and tar shampoo + oral whey protein with starch once a day. This group dissolves a full tablespoon (10 grams) of the placebo in 1 glass of warm water and drinks it in the morning about 30 minutes before breakfast. After drinking the medicine, the patient should walk 100 steps.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
center for research and training in skin disease and and leprosy
Full name of responsible person
Nasrin Azhang
Street address
No. 415, corner of Naderi St., Shahid Taleghani St.
City
Tehran
Province
Tehran
Postal code
638314155
Phone
+98 21 8897 2221
Fax
+98 21 8896 3804
Email
crtsdl@tums.ac.ir
Web page address
https://crtsdl.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Hossein Ayati
Street address
Tehran University of Medical Sciences Headquarters, Qods Corner, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 6640 5666
Email

tumspr@tums.ac.ir

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

Nasrin Azhang

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No. 27, north sarparast st., western taleghani st., felestin squ.

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+98 21 8897 4535

Email

nasrinazhang@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hossein Ayati

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nasrin Azhang

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

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Email

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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

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

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

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

After the publication of the article

To whom data/document is available

All academic people

Under which criteria data/document could be used

After the publication of the article and for other studies and therapeutic use.

From where data/document is obtainable

The person responsible for general accountability

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

Communication with the person responsible for general accountability

Comments