

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of oral administration efficacy of Ganoderma lucidum in amelioration of Psoriasis symptoms (a phase 2A clinical trial)

Protocol summary

Study aim

Evaluation of oral administration efficacy of a product containing Ganoderma lucidum in amelioration of Psoriasis symptoms

Design

Clinical trial without control group, unblinded, in phase 2 on 15 patients.

Settings and conduct

phase 2 clinical trials of efficacy and safety in 15 patients with mild to moderate psoriasis including men and women aged 19 to 59 years after obtaining informed written consent the exact location of the lesion is performed in constant light conditions and the distance of the camera from there. then the itching and burning rate of the selected lesion from 0 to 10 is immotalized by the patient. (0: absence of pain and itching and 10: maximum amount of itching and burning) and psi score of the lesion is determined and recorded by the researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: male or female volunteers with mild to moderate psoriasis patients between 19 and 59 years old healthy physical condition informed signature and consent Exclusion criteria: having any systemic disease that affects the skin using any topical or oral product to treat psoriasis in the last 4 weeks using moisturizers during the study using and cotacting with any chemicals such as solvents during the study without informing the researchers people with cancer pregnant and lactating women

Intervention groups

Main outcome variables

itching difference

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160306026938N7**

Registration date: **2021-05-08, 1400/02/18**

Registration timing: **prospective**

Last update: **2021-05-08, 1400/02/18**

Update count: **0**

Registration date

2021-05-08, 1400/02/18

Registrant information

Name

Mahdi Vazirian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6412 1223

Email address

vazirian_m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of oral administration efficacy of Ganoderma lucidum in amelioration of Psoriasis symptoms (a phase 2A clinical trial)

Public title

Effect of Ganoderma lucidum in improving Psoriasis symptoms

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

male or female volunteers with mild to moderate psoriasis patients between 19 and 59 years old healthy physical condition informed signature on consent form

Exclusion criteria:

having any systemic disease that affects the skin using any topical or oral product to treat psoriasis in the last 4 weeks using moisturizers during the study using and cotacting with any chemicals such as solvents during the study without informing the researchers people with cancer pregnant and lactating women

Age

From **19 years** old to **59 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

..Tehran University of Medical Siences

Street address

.Tehran University of Medical Sciences, Qods street corner, Keshavarz Blvd, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-07-16, 1399/04/26

Ethics committee reference number

IR.TUMS.TIPS.REC.1399.044

Health conditions studied**1****Description of health condition studied**

Psoriasis

ICD-10 code

L40

ICD-10 code description

Psoriasis

Primary outcomes**1****Description**

The level of burning and itching

Timepoint

2 and 4 weeks after receiving the medicine

Method of measurement

Asking the patient and psi score

Secondary outcomes**1****Description**

PSI score

Timepoint

At the begining of the intervention and then, 2 and 4 weeks after receiving the medicine

Method of measurement

سنجش اریتم، پوسته ریزی و سختی پوست

Intervention groups**1****Description**

Intervention group: the patient will take one oral capsule, each morning, noon and night.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Center of Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Dr. Saman Ahmad Nasrollahi

Street address

No. 415, Nader Ave. corner, Taleghani Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-chancellor of research and technology
Street address
Central organization of Tehran university of medical sciences, corner of Ghods Ave., Keshavarz
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rmo@tums.ac.ir
Web page address

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
Mahdi Vazirian
Position
PhD of Pharmacognosy
Latest degree
Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Data would be accessible in related dissertation

**When the data will become available and for how
long**

The onset of access from 2021

To whom data/document is available

تمامی افراد

Under which criteria data/document could be used

The documents could be accessible in case of further
experiments

From where data/document is obtainable

Iran, Tehran, Tehran University of Medical Sciences,
Faculty of Pharmacy, Dr. Mahdi Vazirian

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

Personal request

Comments