

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 contacting 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 Sciences

**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 beginning of the intervention and then, 2 and 4 weeks after receiving the medicine

**Method of measurement**

سنجش آرپتم، 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.

**City**

Tehran

**Province**

Tehran  
**Postal code**  
۱۳۱۶۶۱۳۶۷۵  
**Phone**  
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samannasrol@gmail.com

## 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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417653761  
**Phone**  
+98 21 8163 3619  
**Fax**  
**Email**  
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

#### Street address

Pharmacognosy Lab., Second Floor, New building,  
Faculty of Pharmacy, In front of Oruji Alley, 16th A

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

#### Phone

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#### Fax

+98 21 6695 4706

#### Email

vazirian\_m@tums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
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## Person responsible for updating data

#### Contact

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Tehran University of Medical Sciences  
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**Fax**

**Email**

Vazirian\_m@tums.ac.ir

**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**