Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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)

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+98 21 6412 1223

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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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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
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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