The evaluation of the effect of Melissa officinalis syrup (A traditional medicine formula) on the mild to moderate Psoriasis.

Protocol summary

Study aim
The evaluation of the effect of Melissa officinalis syrup (A traditional medicine formula) on the mild to moderate psoriasis

Design
Two arm parallel group randomised trial

Settings and conduct
Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria
Mild to moderate psoriatic patients, with 18 years old age or more.

Intervention groups
12 weeks of intervention with placebo & medication

Main outcome variables
QoL, disease severity

General information

Reason for update
Acronym

IRCT registration information
IRCT registration number: IRCT20191104045326N1
Registration date: 2019-11-09, 1398/08/18
Registration timing: prospective

Email address
a-yargholi@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-21, 1398/08/30

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The evaluation of the effect of Melissa officinalis syrup (A traditional medicine formula) on the mild to moderate Psoriasis.

Public title
The evaluation of the effect of Melissa officinalis syrup (A traditional medicine formula) on the mild to moderate Psoriasis.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
aga>=18 years old

Exclusion criteria:
Age
From 18 years old

Gender
Both

Phase
3

Groups that have been masked
Participant
Outcome assessor
Data analyser

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this research the physician, participants (patients) and the statistician are blinded

Placebo
Used

Assignment
Parallel

Other design features

Secondary IDs
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
No. 10, Khark Ave., Enghelab Ave.

City
Tehran

Province
Tehran

Postal code
0000000000

Approval date
2019-10-23, 1398/08/01

Ethics committee reference number
IR.TUMS.VCR.REC.1397.424

Health conditions studied

1

Description of health condition studied
Psoriasis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
disease severity with Psoriasis Area Severity Index (PASI)

Timepoint
before intervention, 8th and 12th week of intervention

Method of measurement
PASI score sheet

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group:

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Traditional Medicine, TUMS

Full name of responsible person
Alireza Yargholi

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No. 10, Khark Ave., Enghelab Ave.

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Phone
+98 21 6675 4154

Email
alirezayargholi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Deputy Dean for Research

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alirezayargholi@gmail.com

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
Alireza Yargholi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Full name of responsible person
Mohammad Hossein Ayati
Position
Assistant Professor of Traditional Medicine
Latest degree
Specialist
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
No more information is available
When the data will become available and for how long
No more information is available
To whom data/document is available

Person responsible for updating data
Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Alireza Yargholi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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No. 91, Mirdamad Blvd.
City
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Phone
+98 21 2292 2510
Email
alirezayargholi@gmail.com
No more information is available

**Under which criteria data/document could be used**
No more information is available

**From where data/document is obtainable**
No more information is available

**What processes are involved for a request to access data/document**
No more information is available

**Comments**