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

Last update: 2019-11-09, 1398/08/18
Update count: 0

Registration date
2019-11-09, 1398/08/18

Registrant information
Name
alireza yargholi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2292 2510

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:
age>=18 years old

Exclusion criteria:

Age
From 18 years old

Gender
Both

Phase
3

Groups that have been masked
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
000000000
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
Street address
No. 10, Khark Ave., Enghelab Ave.
City
Tehran
Province
Tehran
Postal code
000000000
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
Street address
No. 10, Khark Ave., Enghelab Ave.
City
Tehran
Province
Tehran
Postal code
000000000
Phone
+98 21 2298 8551
Email
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
Traditional Medicine

Street address
No. 91, Mirdamad Blvd.

City
Tehran

Province
Tehran

Postal code
0000000000

Phone
+98 21 2292 2510

Email
alirezayargholi@gmail.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 of Traditional Medicine

Latest degree
Specialist

Other areas of specialty/work
Traditional Medicine

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

City
Tehran

Province
Tehran

Postal code
0000000000

Phone
+98 21 6675 4154

Email
mh-ayati@tums.ac.ir

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
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<th>Answer</th>
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<td>What processes are involved for a request to access data/document</td>
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