Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Explanation of "KALAF" in Persian Medicine, and Assessment of the effects of Melissa Officinalis syrup on Melasma: A Randomized, triple-Blind, controlled clinical trial

Protocol summary

Study aim
Explanation of "KALAF" in Persian Medicine, and Assessment of the effects of Melissa Officinalis syrup on Melasma

Design
The patients are devised in 2 group. In order to keeping allocation balance during the study "Blocked Randomization" is done: The blocks containing 4 members, inclusive every possible status (6 statuses) are created.This blocks are numbered, chosen allocational and lied in series. Sequence of dedication is characterized. His sequence is located in 140 sealed pockets , given to the researcher.

Settings and conduct
En The randomization is done by person who doesn't meet the patients. Intervention is done by researcher. The researcher, patients and statistician are blind about the groups.The patients are visited in centre for research and training in skin diseases , and the outcomes are assessed by photography, vissioface and mexameter.

Participants/Inclusion and exclusion criteria
Inclusion criteria; Melasma diagnosis by dermatologist, female, age>15 years, Exclusion criteria; using local drugs to treatment of melasma in last 2 weeks, association with diseas pensionable to systemic drugs, uncontrolled diabetes, uncontrolled hypothyroidism, hypermenorrhea, chronic diarrhea, oral contraceptive drugs or hormonal drugs during 4 weeks before beginning the study, pregnancy, lactation

Intervention groups
Intervention 1 (Drug); Melissa officinalis syr. 20 gr every day for 3 months and 2 visit with 45 days Interval. Intervention 2 (placebo); Syrup containing water, sugar and caramel 20 gr every day for 3 months and 2 visit with 45 days Interval.

Main outcome variables
Darkness degree of melasma patch - width of melasma patch

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180927041149N1**
Registration date: **2020-01-05, 1398/10/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-05, 1398/10/15**
Update count: **0**

Registration date
2020-01-05, 1398/10/15

Registrant information

Name
Lida Bakhtyari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3770 3934

Email address
mr80216@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2020-06-21, 1399/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Explanation of "KALAF" in Persian Medicine, and Assessment of the effects of Melissa Officinalis syrup on Melasma: A Randomized, triple-Blind, controlled clinical trial

Public title
Effect of Melissa Officinalis syrup on Melasma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Melasma diagnosis by Dermatologist (at the Center for Research and Training in skin disease And Leprosy) Age> 18 years

Exclusion criteria:
Using local treatment for melasma during 2 weals before play at research Using systemic treatment for any systemic disease Diabetes, thyroid disorder, Hypermenorrhea Oral Contraceptive Drugs and hormonal drugs during 4 weals before play at research Pregnancy, Lactation

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients are devised in 2 group. In order to keeping allocation balance during the study "Blocked Randomization" is done: The blocks containing 4 members, inclusive every possible status (6 statuses) are created.This blocks are numbered, chosen allocational and lied in series. Sequence of dedication is characterized. His sequence is located in 140 sealed pockets , given to the researcher.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The randomization is done by person who doesn't meet the patients. Intervention is done by researcher. The researcher, patients and statistician are blind about the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Etics committee of Tehran University Of Medical Science

Street address
Poorsina St., Districct 6,

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2018-09-23, 1397/07/01

Ethics committee reference number
IR.TUMS.VCR.REC.1397.425

Health conditions studied

1

Description of health condition studied
Melasma - Stress Disorders - Sleep Disorders

ICD-10 code
L81.1

ICD-10 code description
Chloasma

Primary outcomes

1

Description
Darkness and width of Melasma patch

Timepoint
At the start of study and 3 month later

Method of measurement
Mexameter - Vissioface

Secondary outcomes

1

Description
Anxiety, Sleep disorder

Timepoint
The first of study and 3 months later

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Melissa Officinalis syrup 10 gr twice a day, inclusive aqueous extract of 3 gr Melissa Officinalis, aqueous extract of 1 gr Fennel fruit, 8 gr Rosa Damascena, sugar.
Category
Treatment - Drugs

2

Description
Control group: Placebo inclusive water and sugar 10 gr twice a day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmadieh Naturopathic Practitioner
Full name of responsible person
Lida Bakhtyari
Street address
Tabriz Alley, North Sarparast Ave, Taleghani St
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3719186817
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Lidabakhtyari@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohamad Ali Sahraian
Street address
Tehran University of Medical science, Ghods St, Keshavarz Blve,
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Fax
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tums_edu@tums.ac.ir
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
Lida
Position
Ph.D student
Latest degree
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Traditional Medicine
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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