

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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 divided into 2 groups. In order to keep allocation balance during the study "Blocked Randomization" is done: The blocks containing 4 members, inclusive of every possible status (6 statuses) are created. These blocks are numbered, chosen allocationally and listed in series. Sequence of allocation is characterized. This sequence is located in 140 sealed pockets, given to the researcher.

Settings and conduct

En The randomization is done by a person who doesn't meet the patients. Intervention is done by the researcher. The researcher, patients and statistician are blind about the groups. The patients are visited in the center for research and training in skin diseases, and the outcomes are assessed by photography, visioface and Mexameter.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Melasma diagnosis by dermatologist, female, age > 15 years, Exclusion criteria; using local drugs for treatment of melasma in the last 2 weeks, association with diseases amenable 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 visits with 45 days interval.
Intervention 2 (placebo); Syrup containing water, sugar and caramel 20 gr every day for 3 months and 2 visits 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 weeks before play at research Using systemic treatment for any systemic disease Diabetes, thyroid disorder, Hypermenorrhea Oral Contraceptive Drugs and hormonal drugs during 4 weeks 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 divided in 2 groups. In order to keep allocation balance during the study "Blocked Randomization" is done: The blocks containing 4 members, inclusive every possible status (6 statuses) are created. These blocks are numbered, chosen allocation and listed in series. Sequence of allocation is characterized. This sequence is located in 140 sealed pockets, given to the researcher.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The randomization is done by a person who doesn't meet the patients. Intervention is done by the 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

Ethics committee of Tehran University Of Medical Science

Street address

Poorsina St., District 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 months later

Method of measurement

Mexameter - Visioface

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

Ahmadih Naturopathic Practitioner

Full name of responsible person

Lida Bakhtyari

Street address

Tabriz Alley, North Sarparast Ave, Taleghani St

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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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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

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

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City

Qom

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