Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Effectiveness of Iranian Medicine Product: Tamarrindus Indica L. Syrup (Somalax) Compared to Placebo on Patients with Mild to Moderate Acne: A Triple_Blind Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of efficacy of Somalax syrup (Iranian medicine product) in comparison with placebo in patients with mild to moderate acne

Design

A randomized controlled clinical trial with parallel, triple blind, randomized groups

Settings and conduct

A total of 110 volunteers with acne, referred to Ahmadieh Clinic were randomly selected and randomized. Medication and placebo are offered to patients for a 12 weeks period in a similar package as the letters A and B on the door. Patient monitoring continues for 4 weeks after the medication is completed. The patient, the researcher, and the DSMB are unaware of the drug or placebo contents of the packaging.

Participants/Inclusion and exclusion criteria

Entry requirements: Age over 18 years Mild to moderate acne on the face Lack of a history of systemic disease when the patient has to take systemic medication No use of inducing or reducing acne medications in the last 2 weeks No facial surgery in the last month No pregnancy and no breast feeding Willingness to participate in the study Exclusion criteria: Severe acne A history of systemic disease coincides with the patient having to take systemic medication Use of inducing or reducing acne medications in the last 2 weeks Pregnancy and lactation Gastrointestinal pain and inflammation or inflammatory and ulcer disease in the gastrointestinal tract Bowel movements more than three times a day

Intervention groups

Of the eligible candidates, 110 are enrolled Patients were randomly divided into intervention and control groups Intervention group receive oral somalax syrup 10 ml every 8 hours The control group received placebo at the same dose

Main outcome variables

Acne severity index، Quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191103045318N1**
Registration date: **2020-01-13, 1398/10/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-13, 1398/10/23**
Update count: **0**

Registration date

2020-01-13, 1398/10/23

Registrant information

Name

Razieh Kasraei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8809 9869

Email address

dr.kasraei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of Iranian Medicine Product: Tamarrindus Indica L. Syrup (Somalax) Compared to Placebo on Patients with Mild to Moderate Acne: A Triple_Blind Randomized Clinical Trial

Public title
Effectiveness of Iranian Medicine Product: Tamarrindus Indica L. Syrup (Somalax) on Patients with Acne.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Mild to moderate acne on the face Lack of a history of systemic disease when the patient has to take systemic medication No use of inducing or reducing acne medications in the last 2 weeks No facial surgery in the last month No pregnancy and no breast feeding Willingness to participate in the study

Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study presents drugs and placebo in similar packaging. The only difference is the mark A and B on the packaging The manufacturer knows which symptom is related to the drug and which placebo Participants do not know whether they are taking medication or placebo The researcher does not know if she is taking medication or placebo DSMB is not aware of the type of intervention

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
No. 16, 6th Tower, Sina alley, Iranzamin Blvd., Gharb(Qods) Town

City
Tehran

Province
Tehran

Postal code
1466614143

Approval date
2018-10-29, 1397/08/07

Ethics committee reference number
IR.TUMS.VCR.REC.1397.543

Health conditions studied

1

Description of health condition studied
Acne

ICD-10 code
L70.9

ICD-10 code description
Acne, unspecified

Primary outcomes

1

Description
Acne severity index

Timepoint
At baseline (before intervention) and at 6, 12, and 16 weeks after drug administration

Method of measurement
The lesion is counted by the researcher and placed in the ASI formula

Secondary outcomes

1

Description
Quality of life score

Timepoint
At baseline (before intervention) and 16 weeks after drug administration

Method of measurement
DLQI Quality of Life Questionnaire

Intervention groups

1

Description
Intervention group:Iranian medicine product, Somalax syrup (83.3 mg per hl, yellow herb 41.7 mg, jujube 8.20 mg, floss 8.20 mg, red sugar 8.50 mg, Indian spice 5.62

mg) Grams, vinegar 41.7 mg, honey 150 mg), 10 cc each 8 hours for 12 weeks at the laboratory of the Faculty of Pharmacy, University of Tehran

Category

Treatment - Drugs

2

Description

Control group: To make the placebo, mix the water with enough sugar and heat to a consistency, then add turmeric and brown edible oils.Dosage: 10 cc every 8 hours, for 12 weeks, Faculty of Pharmacy, University of Tehran

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahmadieh clinic of Iranian traditional medicine

Full name of responsible person

Razieh Kasraei

Street address

No.27, Sarparast Ave., clinic of Iranian traditional medicine

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shokoofeh Nikfar

Street address

No. 605, Qods Ave., Keshavarz Blvd

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1417653761

Phone

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Email

rcco@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

Razieh Kasraei

Position

Iranian Traditional Medicine Specialist Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Razieh Kasraei

Position

Phd Student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All potential participant data is shared after unidentifiable individuals
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
The data will be available to researchers working in academia and in the industry and can apply for it.
Under which criteria data/document could be used
For scientific studies
From where data/document is obtainable
Razieh Kasraie Email: dr.kasraei@yahoo.com Phone Number: 09178932624
What processes are involved for a request to access data/document
After reviewing the applicant's request and making sure the data is used for scientific studies, the identifiable data of the study participants will be made available to the applicant.
Comments