

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation the effect of Jujube fruit (Ziziphus jujuba L) on skin hyperpigmentation comparison to placebo control; a double blind randomized clinical trial

Protocol summary

Study aim

Evaluation the effect of jujube fruit (Ziziphus jujuba L) on skin hyperpigmentation comparison to placebo control; a double blind randomized clinical trial

Design

Clinical trail with double blind, randomized and phase 2 will be preformed on 46 patients. Clinical trail will be design with parallel groups (placebo and medication). Random Chain Generation performed using by R-CRAN version 3.2.3. Using random permutation blocks will be made blocks (the size of each block is 4) for a total of 46volunteers (1: 1 ratio). The codes will be labeled on the drugs.

Settings and conduct

The study on hyperpigmentation was performed at the Center for Education and Research in Dermatology and Leprosy. Volunteers are divided into two groups: drug and placebo. Volunteers consume 1 tablespoon syrup twice a day for 8 weeks. Pictures from the face are taken by visioface device once before entrance and after 8 weeks. The drug is given to the volunteers by one of the staff and the same explanation is given to each of them.

Participants/Inclusion and exclusion criteria

Age; Skin type; Use of hormonal drugs; Use of topical lightening products; Allergy to components of product; History of any deep peeling of the facial skin; Difficulty in swallowing; Smoking; Pregnancy; Breast feeding; Systemic disease;

Intervention groups

Participants were divided into two groups: medication (extracted from jujube fruit) and placebo.

Main outcome variables

Reduce the number of spots on the skin, reduce the size and its percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N10**

Registration date: **2021-01-14, 1399/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-14, 1399/10/25**

Update count: **0**

Registration date

2021-01-14, 1399/10/25

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8190

Email address

firozali@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-28, 1399/07/07

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation the effect of Jujube fruit (Ziziphus jujuba L) on skin hyperpigmentation comparison to placebo control; a double blind randomized clinical trial

Public title
Evaluation the effect of jujube fruit on skin hyperpigmentation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Skin Type (III -IV) Aged between 18 to 60 years Signed informed consent voluntarily and knowingly
Exclusion criteria:
Use any light sensitive drug within 3 months prior to the study Active skin disease at test area: rosacea, atrophy, acne, eczema Use of topical lightening products like AHA ,BHA and retinoid components within 21 days prior to the study Documented allergies to components of test product Use of contraceptive or any hormonal drugs History of laser treatment or dermabrasion or deep facial peels within the past 3 months difficulty swallowing (a condition that could impact digestion and/or absorption) Active smoker (last 1 years) Current pregnancy/ breast feeding Systemic disease (diabetics, hepatic disease, uncontrolled hypothyroidism)

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Chain Generation performed using by R-CRAN version 3.2.3. Using random permutation blocks will be made blocks (the size of each block is 4) for a total of 46volunteers (1: 1 ratio). The codes will be labeled on the drugs. After ensuring the volunteer's eligibility and signing the informed consent form, a nurse will receive a code from the study site which will be used for random allocation of the drug to the candidate. The related drug will be given for the volunteer. In this way, the volunteers fall into one of the two intervention groups and the volunteers' group and the type of drug they receive will not be disclosed to researchers or the study team.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the main researcher is responsible for taking photo from visioface device. In order to keep

blinding study, volunteers receive drug by one of staff according to random numbers table. Staff give the same explanations to each of the volunteers.

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
First Floor., School of Medicine., Building No., 1 North Door of Tehran University., Poursina St.
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2020-09-21, 1399/06/31
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.509

Health conditions studied

1

Description of health condition studied
hyperpigmentation
ICD-10 code
L81.4
ICD-10 code description
Other melanin hyperpigmentation

Primary outcomes

1

Description
The numbers of skin spots, its size and percentage
Timepoint
At the beginning and after 8 weeks
Method of measurement
Visioface device

Secondary outcomes
empty

Intervention groups

1

Description

1: Intervention group: jujube syrup, 1 tablespoon (7.5 cc), twice a day, 8 weeks

Category

Treatment - Drugs

2

Description

Control group: 1 tablespoon (7.5 cc), twice a day, 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for Research and Training in Skin Diseases
And Leprosy

Full name of responsible person

Alireza Firooz

Street address

Shahid Taleghani St., Corner of Naderi St.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Fax

Email

Firozali@sina.tums.ac.ir

Web page address

Http://crtSDL.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jarf Anishan Navid Salamat company

Full name of responsible person

Saman Ahmad Nasrollahi

Street address

Corner of Naderi St., Shahid Taleghani St., Tehran

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8896 2981

Fax

Email

Samannasrol@gmail.com

Web page address

Http://crtSDL.tums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Jarf Anishan Navid Salamat company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ensiye Aafi

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Pharmacy in Persian medicine

Street address

No. 24 and 26, 6th Alley (Shahid Rahmati Bahmbari).,
Valiasr Square., Tehran

City

Tehran

Province

Tehran

Postal code

1594733711

Phone

+98 21 8889 6836

Email

ensiye_affi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Corner of Naderi St., Shahid Taleghani St., Tehran

City

Tehran

Province

Tehran

Postal code

1416613675

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+98 21 8897 2220

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Phone

+98 21 8889 6836

Fax**Email**

Ensiye_affi@yahoo.com

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

Tehran University of Medical Sciences

Full name of responsible person

Ensiye Aafi

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Pharmacy in Persian medicine

Street address

No. 24 and 26, 6th Alley (Shahid Rahmati Bahmbari)., Valiasr Square., Tehran

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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available