

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Consideration of the effect of an eye cream *Artemisia absinthium* L. on eye darkness; a double blind randomized clinical trial

Protocol summary

Study aim

Consideration of the effect of *Artemisia absinthium* L. on eye darkness; a double blind randomized clinical trial

Design

Randomized double blind with parallel control group clinical trial

Settings and conduct

In Center for Research and Training in Skin Diseases And Leprosy, randomized double blind clinical trial will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1)Suffering from eye darkness 2)Interesting to participate in this study 3)Age 18-65 both sexes 4)Suffering from eye darkness more than 6 month Exclusion criteria: 1)Pregnancy 2)lactation 3)Use of pilling procedure during the 6 last month 4)Use of microdermabrasion and laser 3 months prior to the study 5)Use of laser 3 months prior to the study 6)Use of solarium or sunbathing and sunburn 3 months prior to the study 5)Documented allergies to components of this cream 6)Use of drugs for skin diseases.

Intervention groups

Using cream with active component Using placebo eye cream without active component as control

Main outcome variables

Reduction of eye darkness will be detected with physical examination an Mexameter.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190413043259N1**

Registration date: **2019-11-03, 1398/08/12**

Registration timing: **retrospective**

Last update: **2019-11-03, 1398/08/12**

Update count: **0**

Registration date

2019-11-03, 1398/08/12

Registrant information

Name

Hanan Hamdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8899 5556

Email address

hamdi.h@kar.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-30, 1398/02/10

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Consideration of the effect of an eye cream *Artemisia absinthium* L. on eye darkness; a double blind randomized clinical trial

Public title

Consideration of the effect of *Artemisia absinthium* on eye darkness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from eye darkness Interesting to participate in this study Age 18-65 both sexes Suffering from eye darkness more than 6 month

Exclusion criteria:

Lactation pregnancy Use of solarium or sunbathing and sunburn 3 months prior to the study History of laser treatment or dermabrasion or deep facial peels within the past 3 months

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the sample size of 30 people in each group, based on the randomized block design, 6 blocks with ten sizes were generated using the program at the following address. The information of each block is sorted in a separate pocket and don't open sooner. Based on this allocation B symbol is related treatment and A symbol is related control.

<https://www.sealedenvelope.com/simple-randomiser/v1/lists>

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind clinical trial, which volunteers and researcher are blind about recognition of the cream. blindness is based on packaging and labeling by a Colleague of study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs-Tehran university of Medical Sciences

Street address

VCR-6th floor-The Central Organization Of University-Qods Street- Keshavarz blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-03-18, 1397/12/27

Ethics committee reference number

IR.TUMS.VCR.REC.1398.017

Health conditions studied

1

Description of health condition studied

Eye darkness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduction of darkness after using the medication

Timepoint

At the first- 2 weeks-4 weeks- 8 weeks

Method of measurement

Examination by physician- Test by Mexameter device

Secondary outcomes

empty

Intervention groups

1

Description

1-Intervention group: 30 member volunteer for a 2 month period, apply twice, daily, eye cream (made in the Faculty Of Traditional Medicine) , In small quantities, which has Absinthium extract.

Category

Treatment - Drugs

2

Description

Control group: 2- Control group: 30 member volunteer for a 2 month period, apply twice, daily, eye cream(made in the Faculty Of Traditional Medicine), In small quantities, without Absinthium extract. No more act needed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahmadie Health center

Full name of responsible person

Hanan Hamdi

Street address

No 27-North Sarparast street- Taleqhni Street- Tehran

City

Tehran

Province

Tehran

Postal code

1416663371

Phone

+98 21 8833 5636

Email

SPM@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hanan Hanan

Street address

No 27-North Sarparast Street- Taleqhni Street- Tehran

City

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Province

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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

Hanan Hamdi

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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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

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

No - There is not 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