Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 divice

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

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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

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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

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Person responsible for scientific inquiries

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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