# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## The efficacy of topical castor oil in the treatment of dark circles: a non-randomized uncontrolled clinical trial

### Protocol summary

**Study aim**
Determining the effect of topical castor oil in the treatment of dark circles under the eyes
**Design**
Clinical trial without control group, non-randomized, phase 2 on 15 patients.
**Settings and conduct**
Samples include the patients with dark circles who refer to the Shahid Faghih Dermatology Clinic.
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age over 18 years, Existence of dark circles under the eyes that are not caused by systemic and vascular disease, Approved by a dermatologist.
Exclusion criteria: Patients with systemic diseases such as diabetes, hyperlipidemia, as well as liver, kidney and thyroid diseases, Patents with other dermatological conditions, Use of any systemic medication, Use any topical medication to remove dark circles under the eyes for at least the past month, Hypersensitivity reaction to castor oil, Pregnant and lactating women, Dissatisfaction with participating in the study
**Intervention groups**
Participants in this study receive a cream formulation of castor oil 50% prepared at Shiraz School of Pharmacy. The dose of medication is twice a day for two months.
**Main outcome variables**
The level of darkness of dark circles under eyes

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20150825023753N16**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **prospective**

Last update: **2020-10-18, 1399/07/27**
Update count: **0**
**Registration date**
2020-10-18, 1399/07/27

**Registrant information**
**Name**
Mohammad Mahdi Parvizi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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+98 71 3212 5592
**Email address**
parvizim@sums.ac.ir

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2020-10-22, 1399/08/01
**Expected recruitment end date**
2021-02-18, 1399/11/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The efficacy of topical castor oil in the treatment of dark circles: a non-randomized uncontrolled clinical trial

**Public title**
The efficacy of topical castor oil in the treatment of dark circles
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age over 18 years Existence of dark circles under the

eyes that are not caused by systemic and vascular disease Approved by a dermatologist
**Exclusion criteria:**
Patients with systemic diseases such as diabetes, hyperlipidemia, as well as liver, kidney and thyroid diseases Patents with other dermatological conditions Use of any systemic medication 75/5000Use any other topical medication to remove dark circles under the eyes for at least the past month Hypersensitivity reaction to castor oil Pregnant and lactating women Dissatisfaction with participating in the study

**Age**
From **18 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **15**
**Randomization (investigator's opinion)**
N/A
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Single
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Medical School of Shiraz University of Medical Sciences
**Street address**
Medical School of Shiraz University of Medical Sciences
**City**
Shiraz
**Province**
Fars
**Postal code**
7134845794
**Approval date**
2020-07-20, 1399/04/30
**Ethics committee reference number**
IR.SUMS.MED.REC.1399.246

## Health conditions studied

**1**

**Description of health condition studied**
Dark circles under eyes
**ICD-10 code**
H02.71
**ICD-10 code description**
Chloasma of eyelid and periocular area

## Primary outcomes

**1**

**Description**
The level of darkness of dark circles
**Timepoint**
The level of darkness is measured at the beginning of the study, then one month and two months later.
**Method of measurement**
Using Visioface 1000D

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Participants in this study receive a cream formulation of castor oil 50% prepared at Shiraz School of Pharmacy. The dose of medication is twice a day for two months.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Faghihi Dermatology Clinic
**Full name of responsible person**
Dr. Nasrin Saki
**Street address**
Shahid Faghihi Hospital, Zand Avenue
**City**
Shiraz
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**Postal code**
71348466114
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nasrinsa85@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Abbas Rezaianzadeh
**Street address**
7th floor,Vice Chancellor of Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
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vcrdep@sums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shiraz 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**
Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Mahdi Parvizi
**Position**
Assisstant professor
**Latest degree**
Ph.D.
**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

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Demographic data and the result of the clinical trial
**When the data will become available and for how long**
One year later
**To whom data/document is available**
Researchers
**Under which criteria data/document could be used**
After publication of the extracted article of the clinical trial
**From where data/document is obtainable**
Sending Email to the researchers
**What processes are involved for a request to access data/document**
Sending the request via the email
**Comments**