

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of the effect of crocin of saffron on sleep quality, general health and happiness in elderly population

Protocol summary

Study aim

The aim of this study was to determine the effect of saffron crocin on sleep quality, general health and happiness in the elderly.

Design

Study design: Clinical trial with control group, with parallel groups, triple blind, randomized, phase 3 on 70 patients. Coin toss will be used for randomization.

Settings and conduct

70 elderly referring to health centers affiliated with Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. In this way, the days of the week will be divided into two groups: even and odd, the elderly will be in one group on even days and the individual will be in another group on odd days. In this study, investigators, study participants, and Statistical Analyst will not know the type of supplement prescribed for the patient until the end of the data analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the intervention and Ability to communicate verbally
Exclusion criteria: History of allergy to saffron plant products and Complaints of known psychological illness and Alzheimer

Intervention groups

Intervention: elderly will be assigned to receive either crocin (n=35) or placebo (n=35)

Main outcome variables

Pittsburgh Sleep Quality (Primary outcome), Goldberg Public Health and Oxford Happiness (Secondary outcomes) will be measured at the beginning of the study; at the end of the fourth week and one month after the last day of intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200616047800N1**

Registration date: **2020-08-09, 1399/05/19**

Registration timing: **prospective**

Last update: **2020-08-09, 1399/05/19**

Update count: **0**

Registration date

2020-08-09, 1399/05/19

Registrant information

Name

Narges Naseri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

sadeghi.h@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-11, 1399/05/21

Expected recruitment end date

2020-10-12, 1399/07/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of crocin of saffron on sleep quality, general health and happiness in elderly population

Public title

The effect of crocin of saffron on sleep quality, general health and happiness in elderly population

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the intervention Ability to communicate verbally Get a score of 22 or higher on the general health questionnaire, score 5 and above on the sleep quality questionnaire and a score of 42 or less on the happiness questionnaire at the beginning of the study

Exclusion criteria:

History of allergy to saffron plant products Complaints of known psychological illness and Alzheimer's Taking crocin and antioxidant supplements during the last 3 months before the intervention

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The days of the week will be divided into two groups: even and odd, the elderly will be in one group on even days and the individual will be in another group on odd days.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, investigators, study participants, and Statistical Analyst will not know the type of supplement prescribed for the patient until the end of the data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical

Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2020-06-07, 1399/03/18

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1399.011

Health conditions studied

1

Description of health condition studied

Mental health

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Happiness

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Quality of sleep

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of sleep

Timepoint

At the beginning of the study, 4 and 8 weeks after intervention

Method of measurement

The Pittsburgh Sleep Quality Index

2

Description

General Health

Timepoint

At the beginning of the study, 4 and 8 weeks after intervention

Method of measurement

Goldberg General Health

Secondary outcomes

1

Description

Happiness

Timepoint

At the beginning of the study, 4 and 8 weeks after intervention

Method of measurement

Oxford Happiness

Intervention groups

1

Description

Intervention group: Crocin capsule, two oral 15 mg capsule, twice a day for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: placebo capsule, two oral 15 mg capsule, twice a day for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Health Center

Full name of responsible person

Mohammad Afshar

Street address

Kashan University of Medical Sciences, 5th kilometer of Qotb -e Ravandi Blvd, Kashan Kashan

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8814187159

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Email

SADEGHI_H@SKUMS.AC.IR

Web page address

<http://www.kaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafshe

Street address

Kashan University of Medical Sciences, 5th kilometer of Qotb -e Ravandi Blvd, Kashan Kashan

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Afshar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kashan University of Medical Sciences, 5th kilometer of Qotb -e Ravandi Blvd, Kashan Kashan

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Mohammad Afshar
Position
Associate professor
Latest degree
Ph.D.
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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

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

At the end of the intervention, unidentified data will be disseminated.

When the data will become available and for how long

The data access period will start after the intervention.

To whom data/document is available

The data of this study will be made available to academic researchers and industry professionals.

Under which criteria data/document could be used

Unidentifiable study data for use in industry and meta-analytical studies will be made available to academic researchers and industry professionals.

From where data/document is obtainable

To access the study data, send a message to afshar_m_1344@yahoo.com or refer to Kashan University of Medical Sciences.

What processes are involved for a request to access data/document

After sending a written request to the main person in charge of this project (Dr Mohammad Afshar) and explaining the purpose of obtaining the study data, unidentified data will be provided to her.

Comments