Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessing thee effect of Saffron in post operative cognition disorder (POCD) and delirium, in post CABG patients

Protocol summary

Summary

This is a double blind randomized clinical trial with sample size of 130 patients who undergo on-pump coronary artery bypass surgery at Tehran Heart Center. Patients must have more than 70 score in Wechsler memory scale exam. After obtaining informed consent, patients will be randomized to two different groups. Patients in case group will receive 30 mg saffron per day, three days before surgery till next three months. Patients in control group will be give placebo with the same pattern as case group. Wechsler memory scale test will be done for all patients at three days before surgery, one week after surgery and three months later. Then the scores will be compared between these groups. Furthermore, during the hospitalization, patients will be assessed by a psychologist for detecting delirium.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408071556N63**
Registration date: **2014-10-29, 1393/08/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-29, 1393/08/07

Registrant information

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Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences -Govermental

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing thee effect of Saffron in post operative cognition disorder (POCD) and delirium, in post CABG patients

Public title

Effect of Saffron on reducing recognition problems after cardiac surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age between 30 to 70 year-old. Patients who undergo on-pump cardiac surgery. Patients who have more than 70 in Wechsler memory scale. Exclusion criteria: Patients who do not give informed consent. Patients who undergo off-pump cardiac surgery. Patients who undergo valvular surgery. Patients who are on Warfarin. Patients with severe arrhythmia. Patients who have hypersensitivity to Saffron.

Age

From **30 years** old to **70 years** old

Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard
City
Tehran
Postal code
Approval date
2013-11-05, 1392/08/14
Ethics committee reference number
92-02-30-23285

Health conditions studied

1

Description of health condition studied
Cognitive disorders
ICD-10 code
R48.1
ICD-10 code description
Other and unspecified symptoms and signs involving cognitive functions and awareness

Primary outcomes

1

Description
Wechsler memory scale score
Timepoint
Before intervention, one week after surgery, and three months after surgery
Method of measurement
Scores of Wechsler memory scale will be compared

Secondary outcomes

1

Description
Delirium
Timepoint
After intervention and during hospitalization
Method of measurement
Standard Delirium Rating Scale

Intervention groups

1

Description
Participants in case group will receive 30 mg Saffron/day orally (as two 15 mg capsules of Saffron). Saffron will be given to them from 3 days before surgery to 3 months after that.
Category
Treatment - Drugs

2

Description
Participants in control group will receive 30 mg placebo/day (as two capsules of 15 mg placebo). Placebo will be given to them from 3 days before surgery to 3 months after that. The shape, size and color of Saffron and placebo capsules will be same.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Dr. Seyed Hesameddin Abbasi
Street address
Tehran Heart Center, North Kargar Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person

Dr. Masoud Younesian

Street address

Ghods Street, Keshavarz Boulevard

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Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran Heart Center

Full name of responsible person

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Position

PhD candidate

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Medicine, Tehran university of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty