

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jan 2020

Evaluation the Effects of Valerian and Placebo on Prevention of Cognitive Impairment after Coronary Artery Surgery

Protocol summary

Summary

The aim of this study was to determine the effects of valerian on prevention of cognitive impairment after coronary artery surgery. This study was done in the Cardiothoracic Surgery and Anesthesiology Departments at Mazandaran Heart Center. In this randomized, double-blind trial, 60 patients aged between 30-70 years, scheduled for elective coronary artery surgery using cardiopulmonary bypass, were recruited into the study. Patients were randomized into two groups who received either valerian tablet (containing valerian 1060Mg, the product of the Goldaru Herbal Company, Esfahan, Iran) or placebo every twelve hours. The neurocognitive test used in this study was the "Mini Mental State Examination". The test was done on the day before, ten days and two months after the operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311104190N2**
 Registration date: **2013-11-27, 1392/09/06**
 Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-27, 1392/09/06

Registrant information

Name

Hadi Darvishi Khezri

Name of organization / entity

Islamic Azad University

Country

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University, Sari Branch

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-11-11, 1392/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Effects of Valerian and Placebo on Prevention of Cognitive Impairment after Coronary Artery Surgery

Public title

Effects of Valerian on Prevention of Cognitive Impairment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients aged between 30-70 years. 2. Coronary artery bypass surgery with cardiopulmonary bypass Exclusion criteria: 1. Other simultaneous cardiac surgery (e.g., Valve replacement) 2. Symptomatic cerebrovascular disease 3. Alcoholism 4. Psychiatric illness (any clinical diagnosis requiring therapy) 5. Drug abuse 6. Hepatic insufficiency (liver function tests >1.5 times the upper limit of normal) 7. Severe pulmonary insufficiency (requiring home oxygen therapy) 8. Renal failure (serum creatinine >2mg/dl) 9. Reluctance to do a cognitive test performance 10. Previous heart surgery 11. Preoperative left ventricular ejection fraction <30% 12. Sensitivity to valerian

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics committee of Islamic Azad University, Sari Branch

Street address

See Road Street, Islamic Azad University, Sari, Mazandaran

City

Sari

Postal code

4816119318

Approval date

2013-05-19, 1392/02/29

Ethics committee reference number

5-7625

Health conditions studied

1

Description of health condition studied

Cognitive Impairment

ICD-10 code

F06.8

ICD-10 code description

Other specified mental disorders due to brain damage and dysfunction and to physical disease

Primary outcomes

1

Description

Cognitive Impairment

Timepoint

Before intervention-ten days after beginning of intervention-two month after beginning of the intervention

Method of measurement

Mini Mental State Examination

Secondary outcomes

1

Description

Any reaction to valerian

Timepoint

Ten days after beginning of intervention-two month after beginning of the intervention

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Valerian tablet, 530mg, every twelve hours for two months.

Category

Prevention

2

Description

Control group: Placebo tablet, every twelve hours, for two months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran Heart Center

Full name of responsible person

Dr Abolfazl Firuzian

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad University, Sari Branch

Full name of responsible person

Dr Abbas Rezaei

Street address

See Road Street, Islamic Azad University, Sari, Mazandaran

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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

Vice chancellor for research, Islamic Azad University, Sari Branch

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**

Islamic Azad University, Sari Branch

Full name of responsible person

Hadi Darvishi Khezri

Position

MSc

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Abolfazl Firuzian

Position

Anesthesiologist

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Web page address**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*