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
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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
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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

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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