

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jan 2020

The effect of Valerian capsule on sleep quality in patients with coronary artery bypass grafting

Protocol summary

Summary

(1) Objectives: The main goal is to determine the effect of Valerian capsule on sleep quality in patients with coronary artery bypass graft. (2) Design: Design This study is a randomized clinical trial, triple blind, with placebo. The doctor, patient, analyst and researcher were blinded. random numbers table will be used. (3) Setting and conduct: On the second day after cardiac surgery, the patients will receive entry and exit criteria after the necessary training, giving written consent and recording the demographic and surgical data according to the random number table in the placebo and intervention group. (4) Participants including major eligibility criteria: 70 patients from 40 to 80 years of age with non-emergency coronary artery bypass graft surgery and, if allergic, post-surgical complications and death of the patient are excluded. (5) Intervention: In the complement or intervention group, 35 patients will receive 530 mg capsules of valerian fluid from the second day after surgery every night for one month. In the placebo or control group, there are 35 patients, and in the same way, the placebo will receive capsules containing wheat flour. The four steps (before the intervention - 3 days, 14 days and 30 days later) will be completed by the Pittsburgh Questionnaire. (6) main outcome measures (variables): 1-Sleep mental quality 2-Delay in falling asleep 3- Sleep Sleep efficiency 5- Sleep disorders 6- Use of sleeping medicines 7. Daily functional disorders

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080124080N11**
 Registration date: **2017-09-02, 1396/06/11**
 Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-02, 1396/06/11

Registrant information

Name

Mohammad Gholami

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 509 1279

Email address

gholami.m@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2017-08-11, 1396/05/20

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Valerian capsule on sleep quality in patients with coronary artery bypass grafting

Public title

The effect of Valerian capsule on the quality of sleep in patients with heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : Non-emergency open-heart surgery:age group 40-80 years old! first heart surgery! routine operation in the operating room! use of foot saphenous vein and left internal mammary artery! Post ICU post-operative second day! Alert! lacking Tracheal tube! Understanding the content in Farsi! lack of history of seizure and psychiatric disorders!lack of drug and alcohol! lack of intra-aortic pump:no sleep disorders known prior to admission! EF more than 30%! Patient's satisfaction to participate in the research! Use of the

heart and lung pump :no history of lung, kidney and liver failure: normal creatinine:no use of herbal medicines
Effects on sleeping: not taking hypnotic drugs and antidepressants 3 months before the start of the study:
lack of allergy to valerian and other herbal remedies with sedation such as chamomile: lavender and, etc.: lack of pregnancy at the beginning of the study: blood pressure of more than 100 mmHg . Exit criteria: The complications of surgery during the study: the need for intra-aortic pump: the reluctance to continue to participate in the research: the lack of drug for one week: allergy to valerian in the study time, pregnancy at the time of study: the existence of individual and family crises such as divorce Or the death of the first degree relatives during the study period:the patient's death: severe insomnia: coagulation disorder during the admission: the occurrence of cognitive impairment.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

no

Secondary trial Id

no

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, opposite Kahrizak village, km 5 of Khorramabad Road -

Boroujerd, Khorramabad, Lorestan, Iran

City

Khorramabad

Postal code

6814993165

Approval date

2017-07-31, 1396/05/09

Ethics committee reference number

IR.LUMS.REC.1396.291

Health conditions studied**1****Description of health condition studied**

The quality of sleep in patients with heart surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

sleep

Timepoint

Pre-intervention - 3, 14 and 30 days later intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Interventions in the complement or intervention group are 35 patients who will receive 530 mg capsules of valerian capsules from the second day after surgery every night for one month

Category

Treatment - Drugs

2**Description**

In the placebo or control group, 35 patients and the like, placebo will receive capsules containing wheat flour orally

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Heart Hospital, Shahdad Ayatollah Madani

Full name of responsible person

Halimeh Khaton Zare Elmi

Street address

Shahid Ayatollah Madani Hospital, Kheyradad,
Khorramabad, Lorestan, Iran.

City

Khorramabad

Phone

+98 66 3320 8532

Fax

Email

kh14085@yahoo.com

Web page address

www.lums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Lorestan University of
Medical Sciences

Full name of responsible person

Morovat Taheri Kalani

Street address

Lorestan University of Medical Sciences, opposite
Kahrizak village, km 5 of Khorramabad Road -
Boroujerd, Khorramabad, Lorestan, Iran

City

Khoramabad

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 Lorestan 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

Lorestan University of Medical Sciences

Full name of responsible person

Halimeh Khaton Zare Elmi

Position

Nursing Graduate Student / Nurse

Other areas of specialty/work

Street address

End of the Alley, Negarestan 23, Velayat Boulevard,
22 Bahman Square, Khorramabad, Lorestan, Iran.

City

Khorramabad

Postal code

6817693796

Person responsible for scientific inquiries

Contact

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Mohammad Gholami

Position

PhD in Nursing

Other areas of specialty/work

Street address

Lorestan University of Medical Sciences, opposite
Kahrizak village, km 5 of Khorramabad Road -
Boroujerd, Khorramabad, Lorestan, Iran

City

Khorammabad

Postal code

6814993165

Phone

+98 66 3312 0140

Fax

Email

mohammad13565@yahoo.com :

gholami.m@lums.ac.ir

Web page address

www.lums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Halimeh Khaton Zare Elmi

Position

Nursing Graduate Student / Nurse

Other areas of specialty/work

Street address

End of the Alley, Negarestan 23, Velayat Boulevard,
22 Bahman Square, Khorramabad, Lorestan, Iran.

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Khorramabad

Postal code

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Phone

+98 66 3320 8532

Fax

Email

kh14085@yahoo.com

Web page address

www.lums.ac.ir

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
