

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jan 2020

The effect of Valerian on nurses' anxiety who work in intensive care units of teaching hospitals of Zanjan university of medical sciences.

Protocol summary

Summary

Researches have shown that nurses working in intensive care units suffer a high level of anxiety, this level of anxiety will result in not only negative effects on them, but also in decrease of the care quality and increase of the sanitary-therapeutic costs. So it seems that in case of Valerian effectiveness on reducing the anxiety, it can be recommended to the nurses and other stressful jobs as an alternative method. Accordingly, the present study will be done with the aim of determination of Valerian effectiveness on reducing the anxiety of the nurses working in intensive care units of Zanjan university of medical sciences. The study will be done through the cross sectional clinical trial for two weeks, on the nurses working in morning and evening shifts of intensive care units, who are interested in taking part in the survey. Anxiety decrease will be the main outcome variable in this study. Inclusion criteria are: Working in intensive care units at least for one month; endorsing informed consent form; not having any diagnostic physical and mental disease; not using any other sedatives or relaxant methods; having anxiety according to Spielberger's anxiety inventory. Exclusion criteria are: Not having anxiety according to Spielberger's anxiety inventory; pregnancy and breast feeding; outbreaking severe side effects and participants' no tendency to continue the trial. Herbal Sedamin capsule contained dried roots of Valeriana Officinallis with the dose of 530 mg will be consumed by test group and placebo with the same Shape and dose by control group twice a day for one week. Spielberger's State-Trait anxiety inventory will be used to determine the participants' pre and post-test anxiety levels. Independent t-test and paired t-test will be used for data analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042717454N1**

Registration date: **2014-06-30, 1393/04/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-30, 1393/04/09

Registrant information

Name

kourosh Amini

Name of organization / entity

Zanjan university of medical sciences

Country

Iran (Islamic Republic of)

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+98 243377251314

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan University of Medical Scinces

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Valerian on nurses' anxiety who work in intensive care units of teaching hospitals of Zanjan university of medical sciences.

Public title

Effect of valerian on anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Working in intensive care units at least for one month; endorsing informed consent form; not having any diagnostic physical and mental disease; not using any sedatives, hypnotics, barbitorates,

benzodiazepines, narcotics or alcohol; getting score 20 from Spielberger's anxiety inventory that means having anxiety; not using other relaxant methods like aromatherapy, yoga, acupuncture and so on; not being pregnant or breast feeding. Exclusion criteria: Getting score 20 and less than 20 that means not having anxiety according to Spielberger's anxiety inventory; not using valerian or placebo during study or on the other hand not cooperating; pregnancy diagnosing; outbreaking severe side effects and participant's no tendency to continue the trial.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

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

N/A

Secondary trial Id

N/A

Registration date

empty

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

Ethics committee of Zanjan University of Medical Sciences

Street address

Ethics committee of Zanjan university of medical sciences, Azadi Blvd, Zanjan

City

Zanjan

Postal code**Approval date**

2013-10-19, 1392/07/27

Ethics committee reference number

ZUMS.REC.1392105

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

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

Anxiety

Timepoint

Before intervention and one week after intervention

Method of measurement

Using the Spielberger State -Trate Anxiety inventory

Secondary outcomes**1****Description**

Anxiety decrease

Timepoint

one week after beginning of intervention

Method of measurement

Spielberger's anxiety inventory

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

Before the intervention, all the participants who were interested in taking part in the research and had the inclusion criteria, filled out the Spielberger's anxiety inventory and individuals who had over twenty scores according to this inventory (the sign of anxiety existence), were included in the study. Then, the researcher gave Valerian for the test (intervention) group in the form of 530 mg gelatin covered capsules to take one every morning and night for a week. Whereas, according to the pharmacognosy resources, the Valepotriates in Valerian - effective components in anxiety reduction- are from Iridoids which are unstable compounds; Sedamin capsules were used in this study which contained dried root and risome powder of Valeriana Officinalis, produced by Esfahan Goldaroo company which is more stable in comparison with its other drug forms and standardization procedure is completed by the mentioned company. While in many studies, the extract or a combination of extract and root powder was used with no distinct standardization and stability rate.

Category

Treatment - Drugs

2**Description**

The control group was given the placebo with the same shape, taste, size and period of consumption as Valerian capsules. Regarding the distinct and specific odor of Valerian, Valerian and placebo capsules were stored together separated by a mesh lining, at least for two weeks. All the placebo production and preparation procedure was completed in the pharmaceuticals laboratory of the development center for pharmaceutical products technology units dependent on Tehran university of medical sciences; in this laboratory, ineffective lactose powder was used to fill the placebo capsules. Personal and telephonic follow ups were done by the researcher in order to make sure of participants' drug consumption and the probable side effects investigation. At the end of the period, Spielberger's anxiety inventory was filled out again by the two groups. Questionnaires were gathered and primary and secondary data were analyzed. No payment or premium was received by the participants in this study.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mousavi specialized training and treatment center

Full name of responsible person

Kourosh Amini

Street addressMousavi specialized training and treatment center,
Gavazang Rd, Zanzan**City**

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2**Recruitment center****Name of recruitment center**

Valiasr training and treatment center

Full name of responsible person

Kourosh Amini

Street addressValiasr training and treatment center, After Valiasr Sq,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor for research, Zanzan University of
Medical Sciences**Full name of responsible person**

Dr. Mohammad Masoud Vakilli

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medical sciences, Azadi Blvd, Zanzan**City**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice chancellor for research, Zanzan 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**

Zanzan University of Medical Sciences

Full name of responsible person

Dr. Kourosh Amini

Position

Assistant Professor/Phd

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Masoomeh Najafzadeh

Position

Master of science

Other areas of specialty/work**Street 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*