

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jan 2020

A comparative Study of Valerian consumption in different course on anxiety stress and depression of employed midwives

Protocol summary

Study aim

The main goals: Comparison of the effect of Valerian Consumption in different Courses on anxiety, stress and depression of employed midwives

Design

A clinical trial with a control group, With parallel groups, Double-blind, Accidental

Settings and conduct

This study is a double-blind clinical trial. It will be done on 80 Employed Midwives in hospitals and health Centers in Khorramabad city that have mild to moderate depression, anxiety, stress. Participants were randomly divided into intervention (drug) and placebo groups. In the intervention group 530mg of Valerian capsules (manufactured by Flower medicine Company) is given twice daily for one month. In the control group, placebo was given a 530 mg capsule by the same method. DASS-21 questionnaire and Demographic questionnaire was used for data collection. Results will be compared one week and one month after the intervention.

Participants/Inclusion and exclusion criteria

Midwives working in hospitals or health centers that meet the inclusion criteria are randomly selected in two groups. Inclusion criteria: 1- No use of sedatives and Hypnotic 2- Having mild to moderate anxiety 3- No known mental illness. Exclusion criteria: 1- Failure to complete the questionnaire and daily and timely consumption of Valerian capsule 2- pregnancy.

Intervention groups

Intervention group (drug): 530 mg Saddam's capsule (Valerian root) twice daily for one month Placebo group: 530 mg twice daily capsule for one month

Main outcome variables

Depression; anxiety; stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012440N7**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **prospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Ziba Taghizade

Name of organization / entity

Tehran University of Medical Sciences school of nursing and midwifery

Country

Iran (Islamic Republic of)

Phone

+98 21 8824 4694

Email address

taghizad@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative Study of Valerian consumption in different course on anxiety stress and depression of employed midwives

Public title

Effect of Valerian on depression, anxiety, stress of employed midwives

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: 1- No use of sedatives and Hypnotic 2- Having mild to moderate anxiety 3- No known mental

illness.

Exclusion criteria:

Exclusion criteria: 1-Failure to complete the questionnaire and daily and timely consumption of Sedamin's capsule 2-pregnancy.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

In this method we will have two types of capsules called a and b. The blocking will be four. Capsules a and b will be grouped together in six models. We will give each of the six states a hypothetical number. We'll have a list of clip modes with hypothetical numbers. We'll make cards that write hypothetical numbers 1 to 6 on it. We take it randomly the cards on which the hypothetical numbers are written. Then we will give the capsules a and b based on the pre-arranged list.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the researcher and the participants did not know the type of capsule they received (placebo-drug).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical science

Street address

Tehran University of Science, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-08-23, 1398/06/01

Ethics committee reference number

IR.TUMS.VCR.REC.1398.507

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

2

Description of health condition studied

depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

3

Description of health condition studied

stress

ICD-10 code

Z56.6

ICD-10 code description

Other physical and mental strain related to work

Primary outcomes

1

Description

Depression Score

Timepoint

Before the intervention, one week after the intervention, one month after the intervention

Method of measurement

Dass_21 Questionnaire

2

Description

anxiety score

Timepoint

Before the intervention, one week after the intervention, one month after the intervention

Method of measurement

Dass_21 Questionnaire

3

Description

Anxiety Score

Timepoint

Before the intervention, one week after the intervention, one month after the intervention

Method of measurement

Dass_21 Questionnaire

4**Description**

stress score

Timepoint

Before the intervention, one week after the intervention, one month after the intervention

Method of measurement

Dass_21 Questionnaire

Secondary outcomes

empty

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

Intervention group: (530 mg Valerian capsule) containing the roots of Valerian (manufactured by Flower Drug Company) purchased in Iran 2 times daily for one month.

Category

Treatment - Drugs

2**Description**

Control group: Placebo in the form of 530 mg capsule twice daily for one month for one month.

Category

Treatment - Drugs

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

health center in khorram abad

Full name of responsible person

Syede faze Hashemi nezhad

Street address

Khorram Abad, above Anushirvan Square

City

Khorram Abad

Province

Lorestan

Postal code

1234567890

Phone

+98 66 3323 9941

Email

65136513ff@gmail.com

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

Hospitals of Khorram abad

Full name of responsible person

Syede faze Hashemi nezhad

Street address

Khorram Abad, Moallem Street, Anooshirvan Square

City

Khorram Abad

Province

Lorestan

Postal code

1234567890

Phone

+98 66 3330 0661

Email

65136513ff@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Alireza Nikbakht Nasrabadi

Street address

Vice Chancellor for Research, Tehran University of Medical Sciences. Ghods St. Keshavarz Bv

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6693 3600

Email

fnm@tums.ac.ir

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

syede faeze hashemi nezhad

Position

Master of Midwifery student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

First floor, No. 21, Ghods Avenue, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8893 3768

Email

56136513ff@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Ziba Taghizade

Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Ghods Avenue, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8893 3768

Email

taghizad@tums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

syde faeze hashemi nezhad

Position

Masters of Midwifery Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Ghods Avenue, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8893 3768

Email

65136513ff@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Insufficient information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable