

# 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

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Khorram Abad, Moallem Street, Anooshirvan Square

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**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

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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

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

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**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

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**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**

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**City**

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**Province**

Tehran

**Postal code**

1419733141

**Phone**

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**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