

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of the Effects of Vitamins E, C and D Separately and Synergistically on Pain and Anxiety Score Caused by Withdrawal Syndrome in Patients Who are Candidate for Withdrawal: A Randomized Controlled Clinical Trial

Protocol summary

Study aim

Determining the effect of vitamins E, C and D individually and synergistically on pain syndrome and withdrawal anxiety caused by drug withdrawal

Design

Clinical trial with a control group, with parallel groups, without blinding, randomized, phase 3 on 125 patients. The rand function of Excel software was used for randomization.

Settings and conduct

After obtaining written consent, 125 drug addicts admitted to Mehr Nervi and Psychiatric Hospital in Khorramabad will be assigned to 5 study groups by simple random method without blinding. These groups include control (without treatment), groups receiving one gram of vitamin C, one thousand units of vitamin D, 400 units of vitamin E and the combination of all three vitamins daily for ten days. Demographic and clinical information of patients will be recorded in the initial evaluation. At the beginning and end of the intervention, the pain and anxiety questionnaire is completed for the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmed diagnosis of substance dependence, Men over 18 years old, The emergence of withdrawal syndrome with the diagnosis of a psychiatrist, Has a score of at least 3 in the VAS test, Exclusion criteria: Taking multivitamin, mineral and antioxidant supplements in the last 3 months before starting the intervention, Liver or kidney failure

Intervention groups

Group one includes samples that do not receive any vitamins. Group 2, 3, 4 and 5 are respectively patients who, in addition to receiving standard treatment, receive 1000 vitamin D capsules, 400 vitamin E capsules, 1 gram effervescent vitamin C tablets and the combination of all

three vitamins for ten days.

Main outcome variables

Anxiety and pain from addiction withdrawal

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200721048159N6**

Registration date: **2023-07-08, 1402/04/17**

Registration timing: **prospective**

Last update: **2023-07-08, 1402/04/17**

Update count: **0**

Registration date

2023-07-08, 1402/04/17

Registrant information

Name

Forouzan Ahmadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3312 0239

Email address

ahmadpour.f@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effects of Vitamins E, C and D Separately and Synergistically on Pain and Anxiety Score Caused by Withdrawal Syndrome in Patients Who are Candidate for Withdrawal: A Randomized Controlled Clinical Trial

Public title

Investigating the Effect of Vitamins E, C and D on Symptoms of Withdrawal Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Confirmed diagnosis of opioids and stimulants substances Men over 18 years old The emergence of withdrawal syndrome based on the diagnosis of a psychiatrist a score of at least 3 in the VAS test Performing a TLC test to detect consumption (methadone, morphine, amphetamine and etc..) Consent to participating in the study

Exclusion criteria:

Taking multivitamin, mineral and antioxidant supplements in the last 3 months before starting the intervention Liver or kidney failure

AgeFrom **18 years** old**Gender**

Male

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **125****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization can be done by using the block identifier table and the samples are selected randomly

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Lorestan University of Medical Sciences

Street address

Office of Research Ethics Committee, Vice Chancellor for Research and Technology, Lorestan University of Medical Sciences, Pardis University Complex, 3 km of Khorramabad Road, Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

381351698

Approval date

2022-11-08, 1401/08/17

Ethics committee reference number

IR.LUMS.REC.1401.206

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

Anxiety and pain caused by drug withdrawal in addicted patients

ICD-10 code

F19.3

ICD-10 code description

Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances

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

Pain caused by drug withdrawal according to VAS test

Timepoint

Before the start of the intervention and daily for ten days after the start of the intervention

Method of measurement

Test VAS

2**Description**

Examining anxiety caused by quitting addiction

Timepoint

Before the start of the intervention and daily for ten days after the start of the intervention

Method of measurement

Beck's anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The control group includes samples that do not receive any vitamins

Category

Treatment - Drugs

2

Description

Intervention group1: Intervention group: Patients who, in addition to receiving standard treatment, receive daily dose of vitamin D 1000 unit capsules for ten days.

Category

Treatment - Drugs

3

Description

Intervention group 2: Intervention group: Patients who, in addition to receiving standard treatment, receive daily dose of vitamin E 400 unit capsules for ten days.

Category

Treatment - Drugs

4

Description

Intervention group 3: Patients who, in addition to receiving standard treatment, receive vitamin C effervescent tablets of one gram daily for ten days.

Category

Treatment - Drugs

5

Description

Intervention group 4: Patients who, in addition to receiving standard treatment, receive daily effervescent tablets of vitamin C one gram, vitamin D 1000 units daily and vitamin E 400 units daily for ten days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr Khorramabad Neurological and Psychiatric Hospital

Full name of responsible person

Forouzan Ahmadpour

Street address

3 km of Khorramabad Road, Tehran, Khorramabad, Lorestan

City

khorrarnabad

Province

Lorestan

Postal code

381351698

Phone

+98 66 3324 2430

Email

ahmadpourforoz@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Street address

Lorestan University of Medical Sciences, Pardis University Complex, 3 km of Khorramabad Road, Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3330 0661

Email

publicrelation@lums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Position

Assistant Professor of Clinical Pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Lorestan University of Medical Sciences, Pardis
University Complex, 3 km of Khorramabad Road,
Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3330 0661

Email

ahmadpourforoz@yahoo.com

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Position

Assistant Professor of Clinical Pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Lorestan University of Medical Sciences, Pardis
University Complex, 3 km of Khorramabad Road,
Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

098 66 33300661

Email

ahmadpourforoz@yahoo.com

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Position

Assistant Professor of Clinical Pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Lorestan University of Medical Sciences, Pardis
University Complex, 3 km of Khorramabad Road,
Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3330 0661

Email

ahmadpourforoz@yahoo.com

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

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

Study Protocol

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

Statistical Analysis Plan

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

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

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

Data Dictionary

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