Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of E & C vitamins effects on oxidative stress biomarkers, biochemical parameters, Depression, anxiety and stress in workers exposed to noise, cement dust and silica in SHIRAZ cement plant.

Protocol summary

Study aim

The aim is determine the effect of E and C vitamins intervention on oxidative stress biomarkers, biochemical parameters, Anxiety, depression and stress in workers who exposure to cement dust.

Design

Clinical trial study with 2 group include main intervention group that use E and C vitamins and control intervention group that use placebo, Stratified randomized and double blind with parallel group and include 80 participants

Settings and conduct

Cement dust has many harmful effects on health, So we do this study in Fars cement plant in Shiraz, after choice participant by stratified randomized, Blood sampling perform at the beginning of the work shift at 7 morning. And assessing the oxidative stress level, biochemical parameters before intervention, Also DASS questionnaire filled out. Then vitamins and placebos gives to participants every day along 2 month by our assistant . Researcher and participants not aware of the process of intervention. After two month we will do blood sampling again and will compares the level of oxidative stress, biochemical parameters, with the amount of them before intervention.

Participants/Inclusion and exclusion criteria

Workers with any underlying disease including diabetes, hypertension, heart disease, and kidney disease Workers who take a particular drug or vitamins that has effect on intervention as well as those with less than 5 years job experience Workers who singe a written informed consent

Intervention groups

The main intervention group are participants that use E and C vitamins, And control intervention group are participants that use placebo

Main outcome variables

malondialdehyde, total antioxidant capacity, superoxide dismutase, catalase, silica, alkaline phosphatase, alanine transaminase, aspartate transaminase, high density lipid, low density lipid, triglyceride, total bilirubin, glucose, albumin, creatinine, Anxiety, depression and stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200322046834N1**
Registration date: **2020-04-23, 1399/02/04**
Registration timing: **prospective**

Last update: **2020-04-23, 1399/02/04**
Update count: **0**

Registration date

2020-04-23, 1399/02/04

Registrant information

Name

Faezeh Darabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 2107

Email address

faeze.darabi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-20, 1399/04/30

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of E & C vitamins effects on oxidative stress biomarkers, biochemical parameters, Depression, anxiety and stress in workers exposed to noise, cement dust and silica in SHIRAZ cement plant.

Public title
Assessment of vitamin C and E effect in prevent of disease in workers
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Have at least 5 years job experience sign the written informed consent
Exclusion criteria:
Workers have underlying disease including diabetes, heart disease, kidney disease,gastrointestinal discomfort, and hypertension Using particular drug or vitamins that effect on our intervention
Age
From **20 years** old to **50 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, because the cement plant consisted of different sections, We chose the stratified randomization method, In this study we have seven units in cement plant and With regard to the number of people in each section we chose our community to participate in this study.After stratified randomization and selection of the total sample size (80)select workers we use flip the coin method to choose participants for intervention and the group of vitamins intervention and placebo intervention will be determined.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study we will provide placebo tablet similar to the original tablets content C and E vitamins.Then vitamins and placebos will give to participants by assistant, researcher and participants will not aware of content of tablets.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences Ethics Committee
Street address
No. 11, Second Alley, Second 16 meters Street, Shahid Najafi Quarter, Kermanshah, Iran
City
Kermanshah
Province
Kermanshah
Postal code
6719683515
Approval date
2019-05-07, 1398/02/17
Ethics committee reference number
IR.SUMS.REC.1398.386

Health conditions studied

1

Description of health condition studied
The participant of this study are workers who exposed to harmful agent include cement dust, silica, noise in cement plant
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Malondialdehyde
Timepoint
malondialdehyde measurement will be performed One day befor the intervention, And one day after the intervention.
Method of measurement
Malondialdehyde will measure based on its reaction with thiobarbituric acid reactive substances and will determine by using fluorimetry.

2

Description

Total antioxidant capacity

Timepoint

Total antioxidant capacity measurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

Total antioxidant capacity will be measured by ferric reducing ability in plasma method.

3

Description

Superoxide dismutase

Timepoint

Superoxide dismutase measurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

Activity of superoxide dismutase will measure by superoxide dismutase kit.

4

Description

Catalase

Timepoint

Catalase measurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

Catalase enzyme will determine by catalase kit

5

Description

Alkaline phosphatase

Timepoint

Alkaline phosphatasemeasurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

Alkaline phosphatase will be measured by using standard kit and auto analyzer system.

6

Description

Alanine transaminase

Timepoint

Alanine transaminasemeasurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

alanine transaminase will be measured by using standard kit and auto analyzer system.

7

Description

Aspartate transaminase

Timepoint

Aspartate transaminasemeasurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

Aspartate transaminase will be measured by using standard kit and auto analyzer system.

8

Description

High density lipid

Timepoint

High density lipid measurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

High density lipid will be measured by using standard kit and auto analyzer system.

9

Description

Low density lipid

Timepoint

Low density lipid measurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

Low density lipid will be measured by using standard kit and auto analyzer system.

10

Description

Triglyceride

Timepoint

Triglyceride measurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

Triglyceride will be measured by using standard kit and auto analyzer system.

11

Description

Total bilirubin

Timepoint

Total bilirubin measurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

Total bilirubin will be measured by using standard kit and auto analyzer system.

12

Description

Glucose

Timepoint

Glucose measurement will be performed One day befor the intervention, And one day after the intervention.

Method of measurement

Glucose will be measured by using standard kit and auto analyzer system.

13

Description
Albumin
Timepoint
Albumin measurement will be performed One day befor the intervention, And one day after the intervention.
Method of measurement
Albumin will be measured by using standard kit and auto analyzer system.

14

Description
Creatinine
Timepoint
Creatinine measurement will be performed One day befor the intervention, And one day after the intervention.
Method of measurement
creatinine will be measured by using standard kit and auto analyzer system.

15

Description
Cholesterol
Timepoint
Cholesterol measurement will be performed One day befor the intervention, And one day after the intervention.
Method of measurement
Cholesterol will be measured by using standard kit and auto analyzer system.

16

Description
Depression
Timepoint
The DASS-21 questionnaire will be filled by the participants one day befor intervention and one day after intervention.
Method of measurement
Participants' depression will be obtained by using the total score obtained from filling out the questions.

17

Description
Stress
Timepoint
The DASS-21 questionnaire will be filled by the participants one day befor intervention and one day after intervention
Method of measurement
Participants' stress will be obtained by using the total score obtained from filling out the questions.

18

Description
Anexiety
Timepoint
The DASS-21 questionnaire will be filled by the participants one day befor intervention and one day after intervention.
Method of measurement
Participants' anexity will be obtained by using the total score obtained from filling out the questions.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will 40 participants that use vitamin E and vitamin C, The does of them by arrangement are 400 IU and 500mg. They will use these vitamins for tow month and our assistant give its to them every day after lunch. these vitamins product by Dena Pharmaceutical Company.
Category
Prevention

2

Description
Control group: This group will 40 participants that use placepo for tow month and our assistant give its to them every day after lunch. The content of them is sugar. these placebos product by Dena Pharmaceutical Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fars cement bplant
Full name of responsible person
Alireza Bostanian
Street address
No. 45, Hedayat Street, Postchi Blvd
City
Shiraz
Province
Fars
Postal code
7134953884
Phone
+98 71 3822 8644
Email
faeze.darabi@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Kamyar Zomorodian

Street address
school of health, front of the Bargh club, Razi Blvd, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7134953884

Phone
+98 71 3235 1268

Email
faeze.darabi@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Faeze Darabi

Position
Student

Latest degree
Master

Other areas of specialty/work
Occupational Health

Street address
school of health, front of the Bargh club, Razi Blvd, Shiraz, Iran

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Fars

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Faezeh Darabi

Position
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Latest degree
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Occupational Health

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Faezeh Darabi

Position
Master

Latest degree
Master

Other areas of specialty/work
Occupational Health

Street address
No. 11. Second Alley. Second 16 meters Street. Shahid Najafi Quarter. Kermanshah. Iran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data about participants such as main variable can be share after unrecognizable our participants

When the data will become available and for how long

The time to accesses the information will be four month after publish the results

To whom data/document is available

The information will be available to researchers every where, And we will give the information to people who working in industry.

Under which criteria data/document could be used

After do statistical analyses on our information we publish the data in an article, So it will be available for every one.

From where data/document is obtainable

Individuals can access the article by searching the subjects name that we express, And the article will include the editors email address to answer questions.

What processes are involved for a request to access data/document

After publish the article editor will be online to answer your request, And the process of doing this project and publish article about it has need 8 month nearly

Comments