Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The effect of supplementation vitamin D and vitamin C analoge with endurance physical activity on metabolic syndrome patients

Protocol summary

Study aim

In this study patients will be assessed in order to determine the effects effect of vitamin D and vitamin C supplementation along with endurance physical activity on metabolic according to IDF definition.

Design

This study will be conducted as a randomized controlled trial.

Settings and conduct

Subjects were randomly divided into six groups including 30 subjects (taking vitamin D supplement, vitamin C supplement and placebo).(vitamin D, vitamin D and physical activity, vitamin C, vitamin C and physical activity and finally, placebo and placebo with physical activity) For each patient anthropometric measurements (height, weight and waist circumference) and general characteristics will be assessed at the baseline and end of the study will be filled. 24-h food record questionnaire in order to assessment of food intake and physical activity questionnaire will be complete during the trial. 10 cc fasting blood samples from each patient will be taken at the beginning and end of the intervention.

Participants/Inclusion and exclusion criteria

Participants including major eligibility criteria: Participants having MetS, according to IDF definition, age between 30 and 50 years, both male and female. and Exclusion criteria are: use medications that might affect blood pressure, plasma glucose and lipid profiles throughout the study, they were excluded. The use of any other supplements containing vitamin D and C was also being the exclusion criteria

Intervention groups

Intervention groups will receive vitamin D alone daily 1 vitamin D tablets containing 2000 IU Group two taking Vitamin D and doing physical activity - group three 1 vitamin C tablet containing 500mg with meal alone, group four; taking Vitamin C and doing physical activity. group five taking placebo alone and final group take placebo and doing physical activity daily for 12 weeks.

Main outcome measures (variables): Serum cholesterol, LDL-C, HDL-C, TG, vitamin D and vitamin C, blood pressure and fasting blood glucose in both groups before and after the intervention will be measured.

Main outcome variables

Main outcome measures (variables): Serum cholesterol, LDL-C, HDL-C, TG, vitamin D and vitamin C, blood pressure and fasting blood glucose in both groups before and after the intervention will be measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161110030823N2**
Registration date: **2018-02-01, 1396/11/12**
Registration timing: **retrospective**

Last update: **2018-02-01, 1396/11/12**
Update count: **0**

Registration date

2018-02-01, 1396/11/12

Registrant information

Name

Halgord Farag

Name of organization / entity

Iran

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

00

Expected recruitment start date
2016-03-01, 1394/12/11
Expected recruitment end date
2016-05-01, 1395/02/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of supplementation vitamin D and vitamin C analoge with endurance physical activity on metabolic syndrome patients

Public title
The effect of vitamin D and vitamin C given with outdoor physical activity on obesity, Blood sugar, blood pressure, body cholesterol
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Participants having MetS, according to IDF definition waist circumference ≥ 94 cm for men and ≥ 80 cm for women (triglyceride level ≥ 150 mg/dl), (high density lipoprotein < 40 mg/dl in male and < 50 mg/dl in female), (raised systolic blood pressure ≥130 or diastolic blood pressure ≥ 85 mm Hg), (raised fasting plasma glucose ≥100 mg/dl), age between 30 and 50 years, both male and female, living in Halabja at least 3 years.
Exclusion criteria:
If the study participants use medications that might affect blood pressure, plasma glucose and lipid profiles throughout the study, they were excluded. The use of any other supplements containing vitamin D and C was also being the exclusion criteria. Getting pregnant at the middle of the study and lack of use the supplements for average 10 days, was excluded. For physical activity, if the participants are not follow to recommended time and less than 25 mints, they were being excluded. Individuals with type I and type II diabetes who are taking oral hypoglycemic agents or injecting insulin, or any medical therapy affecting the result, smoker [Light smokers include low-rate daily smokers (< 5 cigarettes per day during their life)], heart failure and those with known chronic renal insufficiency or creatinine ≥1.4 mg/dl; inflammatory gastrointestinal pathology or malabsorption syndrome, neoplasms, alcohol intake >40 g/day; and long-term institutionalization or residing in nursing homes, pregnancy or lactation as well as post-menopausal women and women with surgical menopause was not to be included. Patients with a history of bariatric surgery and use of weight-loss medications was also not be included. those with high triglyceride level > 400 mg/dl, higher systolic blood pressure level >140 and diastolic blood pressure > 90, and finally raised fasting plasma glucose >125 mg/dl was not included.
Age
From **30 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **180**
Actual sample size reached: **21**
Randomization (investigator's opinion)
Randomized
Randomization description
individuals will be in terms of age and gender variables, first blocks of individuals and individuals in each block are completely randomized to the study population.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study blindness method will be used to allocate a training expert to individuals, and the supplement or placebo will be given to him by the subjects he or she will study. Therefore, the study researchers, as well as the subjects studied, will not be informed of the number of subjects
Placebo
Used
Assignment
Parallel
Other design features
The randomization method in this study will be done using the random numbers table. Thus, the matching of individuals will be in terms of age and gender variables, first blocks of individuals and individuals in each block are completely randomized to the study population. The study blindness method will be used to allocate a training expert to individuals, and the supplement or placebo will be given to him by the subjects he or she will study. Therefore, the study researchers, as well as the subjects studied, will not be informed of the number of subjects

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Keshavarz blv., Ghods st. Tehran Tehran Iran, Islamic Republic Of
City
Tehran
Province

Tehran

Postal code

1416643931

Approval date

2016-02-16, 1394/11/27

Ethics committee reference number

IR.TUMS.REC.1395.2832

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

E78.8

ICD-10 code description

lipoprotein metabolic disorder

Primary outcomes

1

Description

serum level of vitamin D

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

ng/ml - specific kits

2

Description

serum level of vitamin C

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

HPLC - mg/dL.

3

Description

systolic blood pressure

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

Mercury Sphygmomanometerwith the accuracy of 1 mmgh

4

Description

diastolic blood pressure

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

Mercury Sphygmomanometerwith the accuracy of 1 mmgh

5

Description

high-density Lipoprotein

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

mg/dL - was measured after precipitation of the apolipoprotein B containing lipoproteins with phosphotungistic acid

6

Description

low-density lipoprotein

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

mg/dL - enzymatic – photometric

7

Description

Triglyceride

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

mg/dL -using triglyceride kits by enzymatic colorimetric tests with glycerol phosphate oxidase

8

Description

Fasting plasma glucose

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

enzymatic colorimetric method using glucose oxidase

Secondary outcomes

1

Description

Body mass index

Timepoint

before treatment and 3 months following end of treatment

Method of measurement

weight / (height)2 - kg/m2

2

Description

waist circumference

Timepoint

before treatment and 3 months following end of treatment

Method of measurement

cm – tapeline

3

Description
parathyroid hormone
Timepoint
before treatment and 3 months following end of treatment
Method of measurement
Elisa

4

Description
calcium
Timepoint
before treatment and 3 months following end of treatment
Method of measurement
chemical analyzers instrument

Intervention groups

1

Description
Vitamin C group: who was take only 500 mg/day vitamin C supplements [Morning Time]
Category
Treatment - Drugs

2

Description
Vitamin C plus physical activity group either morning 7:30 A.M and afternoon after 3:00 PM: who was participated in 30 min/d of endurance physical activity and also will take 500 mg/d vitamin C supplements
Category
Treatment - Drugs

3

Description
Vitamin D group: who was take only 2000 IU/day vitamin D supplements (Morning Time)
Category
Treatment - Drugs

4

Description
Vitamin D plus physical activity group either morning 7:30 PM and afternoon after 3:00 PM: who was participated in 30 min/d of endurance physical activity and also was taken 2000 IU/day vitamin D supplements
Category
Treatment - Drugs

5

Description
Placebo group: A- who were participate in 30 min/d of endurance physical activity and also will take placebo. B- Who were not participated in 30 min/d of endurance physical activity and also was taken placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Halabja Hospital
Full name of responsible person
Salar Hussen
Street address
Mamostayan blv., Sharavani st., Halabja Hospital Center for control of communicable and non-communicable - Iraq
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ms Salehi Rad
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00
Phone
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Email
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Web page address
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
Halgord Ali M.Farag

Position
PhD Student of nutritional science

Latest degree
Master

Other areas of specialty/work
Nutrition

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Other areas of specialty/work
Nutrition

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Web page address

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All participant should have metabolic syndrome based on IDF definition age between 30-50 years both male and female residence in Halabja for long period.

When the data will become available and for how long

After 6 month after the end stage data collection it will be ready (approximately Nov 2016)

To whom data/document is available

This only available for people working in academic institutions

Under which criteria data/document could be used

Any analysis that ethically proved by institute committee

From where data/document is obtainable

E mail address (Halgordtamas@gmail.com)

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

All data available in Excels sheet

Comments

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