Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects of vitamin D and N-acetylcysteine supplementation on the expression of cellular senescence genes and inflammatory factors in the elderly with vitamin D deficiency. A double-blind randomized clinical trial

Protocol summary

Study aim
Comparison of the effects of vitamin D and N-acetylcysteine supplementation on the expression of cellular senescence genes and inflammatory factors in the elderly with vitamin D deficiency.

Design
The clinical trial has 4 intervention groups, with parallel, double-blind, randomized groups, with a sample size of 100 elderly people with vitamin D deficiency. Random allocation will be done in the form of Stratified Randomization.

Settings and conduct
Elderly people with vitamin D deficiency will be classified into one of the four study groups. Before and after the intervention, blood samples will be taken from them and biochemical, molecular and staining tests will be done on the sample.

Participants/Inclusion and exclusion criteria
Elderly people with a body mass index of 25-32 kg/m2; Serum vitamin D deficiency (less than 30 ng/mL); Age over 65 years old; Absence of chronic and acute inflammatory and infectious diseases; No diabetes and thyroid diseases; Absence of Alzheimer's and dementia; No alcohol and smoking; Lack of medication or a disorder that affects vitamin D metabolism (anticonvulsant drugs, antituberculosis drugs, glucocorticoids, HIV drugs). Not receiving vitamin D, NAC and antioxidant supplements in the last three months; Non-participation in other clinical trial studies at the same time as the present study. Exclusion critria: Hypercalcemia (more than 2.6 mmol/L), dysparathyroidism, kidney failure and stones, and long-term treatment with bisphosphonates and corticosteroids. Consumption of less than 90% of prescribed supplements Unwillingness to cooperate during the intervention.

Intervention groups
Group 1. NAC 600 mg/d + 1000 IU/d vitamin D Group 2. 5000 IU/d vitamin D Group 3. NAC 600 mg/d + 5000 IU/d vitamin D Group 4. 1000 IU/d vitamin D.

Main outcome variables
Gene expression of p21, p16, IL-6, β-galactosidase activity, serum IL-6, CRP and TNFα

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230508058120N1**
Registration date: **2023-08-20, 1402/05/29**
Registration timing: **prospective**

Last update: **2023-08-20, 1402/05/29**
Update count: **0**

Registration date
2023-08-20, 1402/05/29

Registrant information

Name
Samira Rastgoo

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of vitamin D and N-acetylcysteine supplementation on the expression of cellular senescence genes and inflammatory factors in the elderly with vitamin D deficiency. A double-blind randomized clinical trial

Public title

Comparison of the effects of vitamin D and N-acetylcysteine supplementation on the expression of cellular senescence genes and inflammatory factors in the elderly with vitamin D deficiency.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly people with a body mass index of 25-32 kg/m2 Serum vitamin D deficiency (less than 30 ng/mL) Age over 65 years old No chronic and acute inflammatory and infectious diseases Not suffering from diabetes and thyroid diseases Not suffering from Alzheimer's and dementia Not receiving alcohol and smoking Not receiving medication or a disorder that affects vitamin D metabolism (anticonvulsant drugs, antituberculosis drugs, glucocorticoids, HIV drugs) Not receiving vitamin D and N-acetyl cysteine and antioxidant supplements in the last three months Non-participation in other clinical trial studies at the same time as the present study

Exclusion criteria:

Hypercalcemia (more than 2.6 mmol/L) Dysparathyroidism, kidney failure and stones, and long-term treatment with bisphosphonates and corticosteroids. Consumption of less than 90% of prescribed supplements Unwillingness to cooperate during the intervention

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria are placed in one of the four study groups using Starified Blocked Randomization (blocks of 4) based on gender and serum vitamin D level (less than 10 ng, 10-20 and 20-30). Since the amount of vitamin D and the gender of people can have a significant impact on the results of the study, to ensure the same distribution of these variables in the groups, random allocation in the form of stratified randomization and using the random block method (permuted block randomization) with quadruple and double blocks will be used. According to the sample size of 100 that has been determined. The block of four and the block of two will be produced using the online site (www.sealedenvelope.com). To apply concealment in the randomization process, unique codes will be used on medicine cans, the software will generate the desired code. As each person enters the study based on the generated sequence, the medicine package in which the desired code is recorded will be allocated to the person. Therefore, before choosing the person, no one will be aware of the type of treatment he will receive. Also, The random sequence generated during the study will be unpredictable.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. Due to the double-blindness of the study, before the start of the study, the sets of cans containing capsules will be prepared by someone other than the researcher. Also, vitamin D and N-acetyl cysteine capsules will be similar in appearance so the researcher does not know the type of capsules each group receives. In addition, the researcher will be unaware of the allocation of the participants in each of the groups until after the end of the intervention period.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Floor 6, Block 2, Shahid Beheshti University of Medical Sciences, Arabi Street, Yemen Street, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-08-07, 1402/05/16

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1402.033

Health conditions studied

1

Description of health condition studied

Vitamin D deficiency

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changes in p21 gene expression

Timepoint

Before and after intervention

Method of measurement

Quantitative Real-time Polymerase chain reaction

2

Description

Changes in p16 gene expression

Timepoint

Before and after intervention

Method of measurement

Quantitative Real-time Polymerase chain reaction

3

Description

Changes in TNFα gene expression

Timepoint

Before and after intervention

Method of measurement

Quantitative Real-time Polymerase chain reaction

4

Description

Changes in IL-6 gene expression

Timepoint

Before and after intervention

Method of measurement

Quantitative Real-time Polymerase chain reaction

5

Description

Changes in beta-galactosidase activity

Timepoint

Before and after intervention

Method of measurement

x-gal staining

6

Description

serum IL-6

Timepoint

Before and after intervention

Method of measurement

ELISA KIT

7

Description

Serum TNFα

Timepoint

Before and after intervention

Method of measurement

ELISA KIT

Secondary outcomes

1

Description

NLR: Neutrophil to Lymphocyte Ratio

Timepoint

Before and after intervention

Method of measurement

Calculation based on complete blood count with Differential test

2

Description

C-Reactive Protein

Timepoint

Before and after intervention

Method of measurement

Elisa kit

Intervention groups

1

Description

First intervention group: 600 mg of N-acetyl cysteine +1000 units of vitamin D daily for 8 weeks.

Category

Treatment - Other

2

Description

Second intervention group: 5000 units of vitamin D daily for 8 weeks

Category

Treatment - Other

3

Description

Third intervention group: 600 mg of N-acetyl cysteine +5000 units of vitamin D daily for 8 weeks.

Category

Treatment - Other

4

Description
Control group: 1000 units of vitamin D daily for 8 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid modarres hospital
Full name of responsible person
Samira Rastgoo
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Samira Rastgoo
Position
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Person responsible for updating data

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

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
Access starts immediately after the publication of the results

To whom data/document is available
All academic researchers

Under which criteria data/document could be used
The data will be made available to other researchers upon reasonable request

From where data/document is obtainable
If the results and the article are published, send an email to the corresponding author.

What processes are involved for a request to access data/document
If the results and the article are published, send an email to the corresponding author.

Comments