

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of vitamin B12 on sleep quality of elderly

Protocol summary

Study aim

Effect of vitamin B12 on elderly sleep quality

Design

A randomized clinical trial. In the available method, 100 elderly people will be selected. Based on the criteria, the researcher will be selected by targeted sampling and will be randomly assigned to two groups A (B12) and B (control group). The randomization sequence will be hidden. There are 100 packets packed in each A and B code. After obtaining informed consent, the researcher removes the desired envelope in accordance with the order and based on the group recorded in the envelope.

Settings and conduct

This research will be conducted in the elderly's home of Rasht. Intervention of the intervention group will be carried out beyond the control and control of the control group.

Participants/Inclusion and exclusion criteria

Entry criteria: Age over 60 years old The desire to participate in the study The absence of a cognitive problem examined by the MMSE and AMTS tools. Dependence on specific alcohol or drugs Not having kidney and liver disease Do not use hypnotic drugs No recent use of multivitamin or similar products Not participating in another research project Exit criteria: Consume less than 70% of the pills Unwilling to continue reading Cure for diseases requiring special treatment

Intervention groups

Supplements is vitamin B12 sublingual tablet with a daily dose of 1000 micrograms per day is manufactured by Webber Naturals, Canada, with a shelf life of 8 weeks. A batch of vitamin B12 sublingual pills will be given daily to the intervention group and will be given to all participants to take a glass of water each time before breakfast to avoid dry mouth, then substitute the tablet for complete resolution. In the control group, routine nursing care will continue and no new intervention will be received.

Main outcome variables

After 8 weeks, the Pittsburgh sleep quality questionnaire

will be completed by both groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100114003064N8**

Registration date: **2018-05-05, 1397/02/15**

Registration timing: **prospective**

Last update: **2018-05-05, 1397/02/15**

Update count: **0**

Registration date

2018-05-05, 1397/02/15

Registrant information

Name

Hossein Bagheri

Name of organization / entity

Shahrood University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 23 3239 5054

Email address

bagheri@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin B12 on sleep quality of elderly

Public title

vitamin B12 in sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 60 years old
The desire to participate in the study
The absence of a cognitive problem examined by the MMSE and AMTS tools
Dependence on specific alcohol or drugs
Not having kidney and liver disease
Do not use hypnotic drugs
No recent use of multivitamin or similar products
Not participating in another research project

Exclusion criteria:

Consumption of less than 70% of the pills
Unwillingness to continue study
Having diseases requiring special treatments

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocks of Volume 4 are used to create randomized sequences because individuals gradually enter the study, and also because the number of allocators is equal to each group. Seniors are based on the criteria of the researcher and to Targeted sampling will be selected and randomly divided into two groups: A (supplement B12) and B (control group). The randomization sequence will be carried out secretly. That is, there are 100 packets packed in each code A and B. After obtaining informed consent and ascertaining that the person is participating in the study, the researcher removes the desired envelope in accordance with the order and proceeds according to the group recorded in the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Because people receive medication, it is not possible to blind people. In order to prevent data leakage, the intervention of the intervention group will be carried out beyond the control and knowledge of the control group. In the pre-intervention phase, the questionnaire will be completed by a person other than the main intervener before assigning the subjects to the study. In this study, the elderly were randomly assigned to four groups of blocks (A) and B (control). After the intervention, the questionnaire is filled in by the same person who knows

the group. To blow up a methodological analyst, the group of people will also be hidden for them.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahroud University of Medical Sciences

Street address

Haft Tir Square, Shahroud University of Medical Sciences

City

shahroud

Province

Semnan

Postal code

3614773955

Approval date

2018-04-30, 1397/02/10

Ethics committee reference number

IR.SHMU.REC.1397.014

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

sleep quality

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

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

Sleep Quality Based on Pittsburgh Sleep Quality Test Score

Timepoint

Before and after the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Supplements used in this study are vitamin B12 sublingual tablets with a daily dose of 1,000 micrograms per day manufactured by Webernear, Canada, with a duration of 8 weeks according to previous studies. A daily subcutaneous supplement of vitamin B12 to humans The intervention group will be given and will be taught to all participants to take a glass of water each time before breakfast to avoid dandruff, then substitute the tablet for complete resolution.

Category

Other

2

Description

Control group: The control group will receive routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Elderly homes in Rasht

Full name of responsible person

Hossein Bagheri

Street address

Rasht, Soleimandarab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad-Hassan Emamian

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Email

emamian@shmu.ac.ir

Web page address

http://research.shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossein Bagheri

Position

Ph.D in Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Hossein bagheri

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossein Bagheri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work**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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available