Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of tolerable high dose of Vitamin B12, B6 & Folate intake on Behavioral and psychological symptoms & Quality of life in patients with Alzheimer's disease

Protocol summary

Study aim
Effects of tolerable high dose of Vitamin B12, B6 & Folate intake on Behavioral and psychological symptoms & Quality of life in patients with Alzheimer's disease.

Design
Two arms parallel-group randomized double-blinded on 60 patients. with concealed randomization sequence.

Settings and conduct
A total number of 60 Alzheimer's type dementia patients (DSM-IV, mild and moderate MMSE score=12-24, Age ≥65) will select from a neurology clinic in Mashhad, Iran who confirmed the included criteria's and filled the informed consent (themselves or a family member) randomly divided into two interventional groups (n=30) and control group (n=30).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Alzheimer's type dementia (DSM-IV, mild and moderate MMSE score=12-24, Age ≥65), no mentioned past medical history of cardiovascular disease, severe renal disease, seizure, anemia or vitamin B deficiency and diabetes mellitus, no recorded family history of cardiovascular disease, Parkinson disease, and any other psychological or neurological disorder. No alcohol or substance abuse and vitamin B interactive drugs at least one month before starting the trial. Patients should have a certain caregiver. Exclusion criteria: missing the interventions for more than 7 days, dying of natural causes, voluntary exclusion from the trial, reported severe side effects of vitamin B during the trial.

Intervention groups
Intervention group (n=30): each patient takes 3 tablets daily (40 mg Tablet of Vitamin B6, 1mg tablet of Vitamin B9, and 1mg tablet of Vitamin B12) after the meal with a glass of water for two months. Control group (n=30): each patient takes 3 placebo tablets matched(size, shape, and color) with the intervention group daily for 2 months.

Main outcome variables
Cognitive symptoms ؛Behavioral and psychological symptoms of dementia ؛ Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211105052972N1**
Registration date: **2021-12-04, 1400/09/13**
Registration timing: **prospective**

Last update: **2021-12-04, 1400/09/13**
Update count: **0**

Registration date
2021-12-04, 1400/09/13

Registrant information

Name
Hanieh Amani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3602 7410

Email address
amanih951@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-21, 1400/09/30

Expected recruitment end date
2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of tolerable high dose of Vitamin B12, B6 & Folate intake on Behavioral and psychological symptoms & Quality of life in patients with Alzheimer's disease

Public title

Effects of tolerable high dose of Vitamin B12, B6 & Folate intake on Behavioral and psychological symptoms & Quality of life in patients with Alzheimer's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Alzheimer’s type dementia (DSM-IV, mild and moderate MMSE score=12-24, Age ≥65) no mentioned past medical history of cardiovascular disease (heart attack, arrhythmia, any heart surgery, and PCI implantation), severe renal disease (Cl Cr. >30 ml/min), seizure, anemia or vitamin B deficiency, and diabetes mellitus (FBS<126 mg/dl). the patient should not have any recorded family history of cardiovascular disease, Parkinson's disease, or any other psychological or neurological disorder. The patient recording must be free of alcohol or any substance abuse and vitamin B interactive drugs at least one month before starting the trial. each Patient should have a certain caregiver (a Nurse - a family member).

Exclusion criteria:

Patients are excluded if they miss the interventions for more than 7 days. death by natural causes. voluntary exclusion. patients with reported severe side effects of vitamin B during the trial. (vitamin B6 neurotoxicity, arrhythmia, ataxia, nausea, diarrhea, skin rash, abdominal discomfort, drowsiness seizure, and severe depression)

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A total number of 60 Alzheimer’s type dementia eligible according to the included criteria and filled the informed consent (themselves or a family member) randomly divided into two interventions (n=30) and a control group (n=30) with Block randomization of two treatment groups A and B, number of blocks = 6, size of blocks = 10, and fixed-size blocks. C the Sequentially numbered, opaque, sealed envelope (SNOSE) technique is for Concealment of allocation. sealed envelopes are the randomization tools.

Blinding (investigator's opinion)

Double blinded

Blinding description

All drugs (placebo and intervention) in both groups are double-blinded and similar in color, size, and shape. neither the participant nor the investigator, caregivers, data collectors, and outcome assessor is aware of the treatment allotted.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of school of medicine-Mashhad University of Medical Sciences

Street address

Khorasan Razavi, Mashhad, University Street - next to Hoveyzeh Cinema - Ghorashi Building - Deputy of Research and Technology

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.206

Health conditions studied

1

Description of health condition studied

Alzheimer’s disease with late onset: Onset usually after the age of 65

ICD-10 code

G30.1

ICD-10 code description

Alzheimer’s disease with late onset: Onset usually after the age of 65

Primary outcomes

1

Description
Cognitive symptoms
Timepoint
before intervention and 8 weeks after intervention
Method of measurement
MMSE score (Questionnaire) and MoCA test (Questionnaire)/

2

Description
BPSD(Behavioral and psychological symptoms of dementia)
Timepoint
before intervention and 8 weeks after intervention
Method of measurement
NPI test(Questionnaire)

3

Description
Quality of life
Timepoint
before intervention and 8 weeks after intervention
Method of measurement
QOL-AD test (Questionnaire)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (n=30): each patient takes 3 tablets daily from their caregivers (40 mg Tablet of Vitamin B6, 1mg tablet of Vitamin B9, and 1mg tablet of Vitamin B12) after the meal with a glass of water for two months. according to ethical problems, In the intervention and control groups, patients receive similar standard main AD medicines.
Category
Treatment - Drugs

2

Description
Control group (n=30): each patient takes 3 placebo tablets from their caregivers daily (shape, size, and color-matched with the case group) right after the meal with a glass of water for 2 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
neurology clinic of Ghaem Hospital
Full name of responsible person
Ali Shoeibi
Street address
Khorasan Razavi, Mashhad, Ahmadabad St., subspecialty clinic of Ghaem Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Street address
Neurology Department - Minus One- Ghaem Hospital - Ahmad Abad Ave - Mashhad
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Nemati
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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NematyM@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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