

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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  $\geq 65$ ) 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  $\geq 65$ ), 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 (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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

99199-91766

##### Phone

+98 51 3840 0000

##### Fax

+98 51 3845 3239

##### Email

shoeibia@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Ali Shoeibi

##### Street address

Neurology Department - Minus One- Ghaem Hospital - Ahmad Abad Ave - Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

99199-91766

##### Phone

+98 51 3842 9828

##### Fax

+98 51 3842 9828

##### Email

shoeibia@mums.ac.ir

#### 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**

Nutrition

**Street address**

Department of Nutrition, School of Medicine, Mashhad university of medical sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91779-48564

**Phone**

+98 51 3800 2361

**Fax****Email**

NematyM@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ali Shoeibi

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

**Street address**

Neurology Department - Minus One- Ghaem Hospital - Ahmad Abad Ave - Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99199-91766

**Phone**

+98 51 3842 9828

**Fax**

+98 51 3842 9828

**Email**

shoeibia@mums.ac.ir

**Person responsible for updating data****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**

Nutrition

**Street address**

Metabolic Syndrome Research Center, Mashhad University of Medical Sciences (MUMS),The University Campus (Paradise Daneshgah), Azadi Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91779-48564

**Phone**

+98 51 3800 2361

**Email**

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