

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Evaluation of effects of vitamin B12 on the serum levels of pro-inflammatory cytokines in the patients with Alzheimer with and without behavioral disorders

#### Protocol summary

##### Summary

The main aim of this study is to evaluate administration of Cobalamin on the serum levels of pro-inflammatory cytokines in the Alzheimeric patients with psychotic symptoms. Alzheimer diagnosis in patients were achieved based on Diagnostic and Statistical Manual of Mental Disorders criteria by history ,clinical examinations, Scan of the Brain , Magnetic resonance imaging and laboratory results combined with mini mental state examination score less than 23. The behavior disorders of the patients were measured using the brief psychiatric rating scale score. Patients suffering from Alzheimer were randomly divided by table of random numbers into four 20-member groups. For elderly in groups 1 and 2, quetiapine and risperidone were prescribed separately, respectively. The other groups are received risperidone or quetiapine combined with a Cobalamin 500 mg daily. Patient's behavior and pain response to treatment was assessed before treatment and after 2 and 8 weeks of study by using the brief psychiatric rating scale test and visual analogue scale for pain and clinical global improvement. ELISA technique will be used for evaluation of serum levels of the cytokines before and after treatment.

#### General information

##### Acronym

alzheimer

##### IRCT registration information

IRCT registration number: **IRCT2015111625067N1**

Registration date: **2016-05-14, 1395/02/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-14, 1395/02/25

##### Registrant information

###### Name

Fattemeh Hosieni

###### Name of organization / entity

Rafsanjan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34258497

###### Email address

hossini1389@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

University of Rafsanjan Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2017-02-19, 1395/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effects of vitamin B12 on the serum levels of pro-inflammatory cytokines in the patients with Alzheimer with and without behavioral disorders

##### Public title

Serum level of inflammatory cytokines in Alzheimer's patients with behavioral disorders and behavioral disorders

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria In this study is: (Alzheimer diagnosis in elderly patients is carried out on basis of clinical interviews; DSM IV diagnosis criteria; medical history; clinical examinations; MRI and brain CT scan results and the mini mental state examination score; Patients who have mini mental score above than are studied; patient with Brief Psychiatric Rating Scale score 30-70) Exclusion criteria (Patients who were taking anti-psychotic medication; has schizophrenia symptoms; preliminary psychotic disorders; delirium; psychoses followed by drug or medication take; Other medical background disorders like B12 deficiency and hypothyroidism; Patients needed to be hospitalized; Patients posed to suicide commitment risk; Other causes of dementia like brain tumors; strokes; normal pressure hydrocephalus; Underlying medical conditions; that may cause behavioral or psychotic symptoms or delirium such as infection, medications with anticholinergic effects; corticosteroid use; or neurological insults is the first step in the decision-making process for treatment. In addition, the patients were discarded from the procedure if they need further medical intervention and other drugs according to their health status or families' remark.

### **Age**

From **64 years** old to **84 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **80**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Rafsanjan University of Medical Sciences

##### **Street address**

Central Organization of Rafsanjan University of Medical Sciences, Rafsanjan University of Medical Sciences, Rafsanjan, Iran

### **City**

Rafsanjan

### **Postal code**

7718796755

### **Approval date**

2016-02-20, 1394/12/01

### **Ethics committee reference number**

IR.RUMS.REC.1394.234

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Alzheimer

#### **ICD-10 code**

G30

#### **ICD-10 code description**

Alzheimer disease

## **Primary outcomes**

### **1**

#### **Description**

Pain

#### **Timepoint**

2week,4week,8week

#### **Method of measurement**

Visual Analogue Scale For Pain Questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Psychiatric symptoms

#### **Timepoint**

Before treatment , 2 weeks and 8 weeks after treatment

#### **Method of measurement**

Brief Psychiatric Rating Scale Questionnaire

## **Intervention groups**

### **1**

#### **Description**

Group of Patients is treated randomly with quetiapine alone, 12.5 mgr in night and rise to 25 to 50 mg according to patient condition

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Group of Patients is treated randomly with risperidone alone, 0.5 mgr in night and rise to 1 to 2 mg daily according to patient condition.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Group of Patients Divided into two groups, one group received quetiapine combined with a cobalamin 500 mg daily.

#### **Category**

Prevention

### 4

#### **Description**

Group risperidone of Patients Divided into two groups, second group received risperidone combined with a cobalamin 500 mg daily.

#### **Category**

Prevention

### 5

#### **Description**

Patients who take risperidone. another group received placebo with risperidone

#### **Category**

Placebo

### 6

#### **Description**

Patients who take quetiapine. another group received placebo with quetiapine.

#### **Category**

Placebo

### 7

#### **Description**

Serum levels of IL-6, IL-8 and TNF- $\alpha$ , as pro-inflammatory cytokines, in all participants will be evaluated using ELISA method in a serum samples. Serum samples were collected from a coagulated blood after centrifuge

#### **Category**

Diagnosis

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Health Centers In The City

##### **Full name of responsible person**

Ali Reza Vakilian

##### **Street address**

Rafsanjan University of Medical Sciences

##### **City**

Rafsanjan

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

#### **Name of organization / entity**

Rafsanjan University of Medical Sciences

#### **Full name of responsible person**

Hamid Hakimi

#### **Street address**

Central Organization of Rafsanjan University of Medical Sciences, RaRafsanjan University of Medical Sciences, Rafsanjan, Iran

#### **City**

Rafsanjan

#### **Grant name**

#### **Grant code / Reference number**

1247

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

Yes

#### **Title of funding source**

Rafsanjan University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

*empty*

#### **Domestic or foreign origin**

*empty*

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Rafsanjan University of Medical Sciences

##### **Full name of responsible person**

Ali Reza Vakilian

##### **Position**

Assistant professor of neurology

##### **Other areas of specialty/work**

##### **Street address**

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## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Alireza Vakillan

**Position**

Assistant Professor Of Neurology

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Fattemeh Hosieni

**Position**

Nurse/MSc

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*