Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Fatemeh Hosseini

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 8497

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 Siences, 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-α, 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 Siences, 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 Vakilin
Position
Assistant professor of neurology
Other areas of specialty/work
Street address
Central Organization of Rafsanjan University of Medical Siences, Rafsanjan University of Medical Sciences, Rafsanjan, Iran
City
Rafsanjan
Postal code
7717933777
Phone
+98 34 3428 0090
Fax
+98 34280071
Email
alirezavakilian66@rums.ac.ir
Web page address
www.rums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Alireza Vakillin

Position

Assistant Professor Of Neurology

Other areas of specialty/work

Street address

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

City

Rafsanjan

Postal code

7717933777

Phone

+98 34 3428 0090

Fax

+98 34280071

Email

alirezavakilian7@gmail.com

Web page address

www.rums.ac.ir

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

Street address

Rafsanjan University of Medical Siences, Ra Rafsanjan University of Medical Sciences, Rafsanjan, Iran

City

Rafsanjan

Postal code

7717933777

Phone

+98 34 3428 0090

Fax

+98 34280071

Email

hossini1389@yahoo.com

Web page address

www.rums.ac.ir

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