

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the effect of Quetiapine and Risperidone with or without Cobalamin in elimination of pain and symptoms of psychosis in Alzheimer's patients

Protocol summary

Summary

The main aim of this study is to evaluate administration of Cobalamin on Reduce pain and behavioral and in the Alzheimer 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

General information

Acronym

RADS

IRCT registration information

IRCT registration number: **IRCT201501101061N18**

Registration date: **2016-05-15, 1395/02/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-15, 1395/02/26

Registrant information

Name

Reza Vazirinejad

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences.

Expected recruitment start date

2015-01-19, 1393/10/29

Expected recruitment end date

2017-04-18, 1396/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Quetiapine and Risperidone with or without Cobalamin in elimination of pain and symptoms of psychosis in Alzheimer's patients

Public title

Comparing the effect of Antipsychotic drugs with or without Cobalamin in elimination of pain and symptoms of psychosis in Alzheimer's patients

Purpose

Treatment

Inclusion/Exclusion criteria

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 **65 years** old to **85 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Ethics

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of 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

2015-02-20, 1393/12/01

Ethics committee reference number

148/20/31/dp

Health conditions studied

1

Description of health condition studied

Alzheimer disease

ICD-10 code

G30

ICD-10 code description

Alzheimer disease

Primary outcomes

1

Description

pain

Timepoint

before treatment , 2 weeks and 8 weeks after treatment

Method of measurement

Visual Analogue Scale for pain Questionnaire

2

Description

psychiatric symptoms

Timepoint

before treatment , 2 weeks and 8 weeks after treatment

Method of measurement

Brief Psychiatric Rating Scale Questionnaire

Secondary outcomes

1

Description

patient progress and treatment response

Timepoint

2 weeks and 8 weeks after treatment

Method of measurement

Clinical Global Impressions scale Questionnaire

Intervention groups

1

Description

one 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

one 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

one group of Patients randomly received Quetiapine 12.5 mg or higher dose ,combined with a monthly 1000 mcgr. vitamin B12

Category

Treatment - Drugs

4

Description

one group of patients randomly received Risperidone 0.5 mg or higher dose combined with 1000 mcgr vitamin B12 per month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers in the city of Rafsanjan

Full name of responsible person

Alireza Vakilian

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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City

Rafsanjan

Grant name

10506

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

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Position

Assistant Professor Of Neurology

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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