Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 39 1822 0097

Email address

pejoheshi@rums.ac.ir

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 Siences, 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
Breif 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
Street address
Central Organization of Rafsanjan University of Medical Siences, RaRafsanjan University of Medical Sciences, Rafsanjan, Iran
City
Rafsanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Siences
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
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 Siences
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
Alireza Vakilian
Position
Assistant Professor Of Neurology
Other areas of specialty/work
Street address
Rafsanjan University of Medical Sciences, Imam Ali blvd. Rafsanjan
City
Rafsanjan
Postal code
7718796755
Phone
+98 34 3425 5900
Fax
+98 34 3425 8294
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 Vakilian
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 Rafsanjan
City
Rafsanjan
Postal code
7718796755
Phone

+98 34 3428 0090
Fax
+98 34280071
Email
alirezavakilian66@rums.ac.ir
Web page address
http://www.rums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Rafsanjan University of Medical Siences
Full name of responsible person
Fattemeh Hosieni
Position
Nurse/Master Of Nursing
Other areas of specialty/work
Street address
Central Organization of Rafsanjan University of Medical Siences, Rafsanjan
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