Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

The effect of adding Mirtazapine to quetiapine on reducing aggression in patients with Alzheimer's dementia

Protocol summary

Study aim
Evaluation of the effect of adding Mirtazapine to Quetiapine on reducing aggression in patients with Alzheimer's dementia

Design
Clinical trial with control group, double-blind, randomized on 52 patients. Randomization using the software

Settings and conduct
Experimental study of double-blind randomized clinical trial Patients: Outpatients referred to the Alzheimer's Association Mafi Clinic and Razi Hospital Blind people: participant-evaluator-researcher-analyst Patients are treated with Quetiapine. After 2-4 weeks, the(Cohen-Mansfield Agitation Inventory) Questionnaire is completed. Patients with a score of 45 or higher are randomly divided into intervention (A) and control (B) groups. Group A is given Mirtazapine in addition to Quetiapine and will continue until the 6th week. Group B is given placebo in addition to Quetiapine . Patients are followed up weekly for 6 weeks. Psychiatric symptoms were recorded based on the CMAI as well as the severity and stage of Dementia according to the (Mini–mental state examination) at the beginning of the study, the end of the 4th week and the 6th week, and in the 6th week the information is statistically analysed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patient with Alzheimer At least two years have passed since the onset of the disease, and the (Cohen-Mansfield Agitation Inventory) test score is more than 45 Exclusion criteria : psychiatric, physical, and neurological disability with a significant impact on patients' cognition, mental retardation , alcohol and substance abuse in the previous 6 months, and other Psychiatric medication.

Intervention groups
Intervention :100-150 mg of Quetiapine and Mirtazapine (84 mg at night, which reached 71 mg at night after one week) control :100-150 mg of Quetiapine and placebo

Main outcome variables
Agitation changes Aggression changes Dementia status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210613051565N1**
Registration date: **2021-07-19, 1400/04/28**
Registration timing: **prospective**

Last update: **2021-07-19, 1400/04/28**
Update count: **0**

Registration date
2021-07-19, 1400/04/28

Registrant information

Name
sahar darvishskandari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2200 7927

Email address
saharskandari1975@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of adding Mirtazapine to quetiapine on reducing aggression in patients with Alzheimer's dementia

Public title
"Effect of Mirtazapine on aggression in patients with Alzheimer"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adult patients (over the age of 18) With Alzheimer's dementia At least two years have passed since the onset of the disease Confirm by a neurologist or psychiatrist with the NIA-AA (2011 National Institute on Aging and Alzheimer's Association) diagnostic criteria assistant. Participant's consent Cohen-Mansfield Agitation Inventory (CMAI) test score more than 45

Exclusion criteria:
No psychiatric disability No physical disability No neurological disability Any disease with significant cognitive Impairment, (mental retardation) No substance abuse in the previous six months No extra psychiatric medication

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Unit randomization happens in the form of blocks consisting of four units. For all six possible permutations, the numbers are associated as below: 1(AABB), 2(ABAB), 3(ABBA), 4(BBAA), 5(BABA), 6(BAAB) . Using a random table, numbers are chosen among those 6 groups to designate the allocated treatment. To continue the process of randomization, a hidden label method was adopted to further encode the blocks. In this method, blocks are numbered using a sequence of random numbers, then the randomly assigned treatment (medicine) is put in each block. The cans/blocks are then handed over to executive agents. Researcher allocates patients to either intervention or standard treatment based on the order of their arrival/reception. Tools: Create a randomized sequence using four random encoded blocks for the participants of the study. Approach: Random selection of the blocks and reading the letters from right to left on labelled blocks based on random sequence. Blocks are of the same weight and shape and prepared by an independent researcher.

Blinding (investigator's opinion)
Double blinded

Blinding description
This clinical trial is blinded so that the participants, the clinician, , principle researcher ,data collector and outcome evaluator do not have any info about the assignment of individuals to the groups. The evaluation of the subjects is done by the external evaluator who is not involved in the research team. The main drug and placebo that are similar (in terms of odour, colour, shape and taste) are placed in similar cans having the same weight by a person who is not a member of the research team. Drugs are coded based on random sequence in two groups (A) and (B) and they are numbred randomly. A unique code is assigned to each patient .The researcher provides the drug to the participant according to the coding

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
University of Social Welfare and Rehabilitation Sciences

Street address
Unit 3 ,No.14,Omidvar Ave.,Haidari St, Zargandeh , Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1916994695

Approval date
2021-06-13, 1400/03/23

Ethics committee reference number
IR.USWR.REC.1400.074

Health conditions studied

1

Description of health condition studied
Alzheimer's dementia

ICD-10 code
G30

ICD-10 code description
Alzheimer's disease

Primary outcomes

1

Description
-Cognitive changes by the MMSE - symptoms of agitation and aggression by the CMAI
Timepoint
In 0,4,6 weeks
Method of measurement
Questionnaire Mini–mental state examination(MMSE) ,Questionnaire Cohen Mansfield Agitation Inventory(CMAI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with entry criteria who have symptoms of agitation or aggression. These patients are treated with Quetiapine(Abidi company) and during 2-4 weeks, the dose of the drug is titrated according to the patient's tolerance and reaches 150-100 mg per day. The Cohen-Mansfield Agitation Inventory questionnaire is then completed for the patient (the patient will be used with the patient to complete information related to this questionnaire). Patients with a score of 45 or higher are randomly divided into intervention (A) and control (B) groups (patients with a score Under 45 are excluded from the study)Group A as the intervention group, in addition to quetiapine drug treatment, receive 15 mg of mirtazapine(Tadbir kala jam company) tablets at night, which will increase to 30 mg after two weeks (48) and will continue until the sixth week.
Category
Treatment - Drugs

2

Description
Control group: Group B as a control group, in addition to Quetiapine(Abidi) drug therapy, is given a placebo tablet(Abidi company), which will be one tablet a night for the first two weeks and two tablets a night after two weeks. The packaging and shape of the two tablets are similar to maintain the blinding of the study. The patients are followed up weekly for six weeks and are monitored by telephone visits for side effects, especially CNS and exacerbation of drowsiness, and patient admissions will be reviewed and excluded if a complication occurs. Psychiatric symptoms were recorded based on the (Cohen-Mansfield Agitation Inventory) scale as well as the severity and stage of dementia according to the(Mini–mental state examination) score at the beginning of the study, the end of the fourth week and the sixth week, and in the sixth week the data are statistically analysed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mafi Clinic, Razi Hospital
Full name of responsible person
Sahar Darvishskandari
Street address
Unit 3, No 14, Omidvar Ave., Heidari St., Zargandeh
City
Tehran
Province
Tehran
Postal code
1916994695
Phone
+98 21 2200 7927
Email
saharskandari1975@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Mehrdad Farrokhi
Street address
6 Ave., Velenjak
City
Tehran
Province
Tehran
Postal code
1985713871
Phone
+98 21 2218 0083
Email
pr@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Sahar Darvishskandari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Unit 3, No 14, Omidvar Ave., Hidarie St., Zargandeh
City
Tehran
Province
Tehran
Postal code
1916994695
Phone
+98 21 2200 7927
Email
saharskandari1975@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Sahar Darvishskandari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Unit 3, No 14, Omidvar Ave., Heidari St., Zargandeh
City
Tehran
Province
Tehran
Postal code
1916994695
Phone
+98 21 2200 7927
Email
saharskandari1975@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Sahar Darvishskandari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Unit 3, No 14, Omidvar Ave., Heidari ST., Zargandeh
City
Tehran
Province
Tehran
Postal code
1916994695
Phone
+98 21 2200 7927
Email
saharskandari1975@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available