

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

Agitation changes Aggression changes Dementia status

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

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		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.	
Scientific title	The effect of adding Mirtazapine to quetiapine on reducing aggression in patients with Alzheimer's dementia	Blinding (investigator's opinion)	Double blinded
Public title	"Effect of Mirtazapine on aggression in patients with Alzheimer"	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
Purpose	Treatment	Placebo	Used
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	Assignment	Parallel
Age	From 18 years old	Other design features	
Gender	Both	Secondary Ids	empty
Phase	3	Ethics committees	
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor • Data analyser	1	
Sample size	Target sample size: 52	Ethics committee	
Randomization (investigator's opinion)	Randomized	Name of ethics committee	University of Social Welfare and Rehabilitation Sciences
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	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

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Unit 3, No 14, Omidvar Ave., Heidari St., Zargandeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Mehrdad Farrokhi

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6 Ave., Velenjak

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1985713871

Phone

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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

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

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Person responsible for scientific inquiries

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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