Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

"Evaluation of the possible effect of berberine supplementation on changes in serum levels of glutamate-dopamin-serotonin and GABA neurotransmitters in dementia patients"

Protocol summary

Study aim
Evaluation of the relationship between berberine supplementation and changes in dopamine, serotonin, glutamate and GABA light transmitters in human patients with dementia

Design
Clinical trial with drug (n = 35), placebo (n = 35) and control (n = 35) groups. Randomized in parallel groups based on ABC permutation blocks and preparation of randomized forms, three-way blind, phase 2 and 3 clinical, sample size 105 patients

Settings and conduct
Divide groups into three similar categories A, B and C. Blinded at the patient level, patient assessment outcome assessor, data analysis physician, drug safety monitoring committee, Valiasr Hospital in Fasa

Participants/Inclusion and exclusion criteria
Inclusion criteria: Completion of DSM_IV diagnostic questionnaires - The same conditions of disease severity - Age of inclusion - Proof of dementia by CT scan, MRI Non-entry conditions: Similar neurological disorders - History of alcohol consumption in the past year - History of gastrointestinal diseases

Intervention groups
Drug group: Capsules containing 300 mg of berberine supplement Pharmacological group: Capsules containing 300 mg of starch Control group: healthy people without receiving treatment protocol

Main outcome variables
GABA amino butyric acid

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211012052739N1**
Registration date: **2021-11-08, 1400/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-08, 1400/08/17**
Update count: **0**

Registration date
2021-11-08, 1400/08/17

Registrant information

Name
Hamidreza Rahmani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-25, 1400/08/03

Expected recruitment end date
2021-11-19, 1400/08/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
"Evaluation of the possible effect of berberine supplementation on changes in serum levels of glutamate-dopamin-serotonin and GABA neurotransmitters in dementia patients"

Public title
"The effect of herbal supplements on neurotransmitters in the formation of dementia"
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion age (at least 65 years) Complete DSM_IV diagnostic questionnaires by a partner specialist Proof of dementia by CT scan, MRI The same conditions as the severity of the disease
Exclusion criteria:
Having similar neurological disorders Alcohol consumption history in the past year History of gastrointestinal diseases
Age
From **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample selection method is randomization based on random blocks in which A, B and C are considered as drugs, placebo and control. It consists of 35 blocks and is selected and placed one after the other, referring to the random Excel numbers of the ABC block.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The drugs are encapsulated by the partner pharmacist in the design according to the principles of pharmacy and are placed in the same packages named A and B. Packages containing the drug are delivered to the patients after the conditions are met for entry into the study and based on the randomized forms. The control group includes healthy people who are according to age and gender according to the group.It is a drug and placebo and is considered to study the normal serum level of neurotransmitters.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Fasa University of Medical Sciences
Street address
Fasa University of Medical Sciences., Ibn Sina Square
City
Fasa
Province
Fars
Postal code
7461791695
Approval date
2021-10-09, 1400/07/17
Ethics committee reference number
IR.FUMS.REC.1400.075

Health conditions studied

1

Description of health condition studied
Dementia
ICD-10 code
F03. 90
ICD-10 code description
Dementia in other diseases classified elsewhere without behavioral disturbance

Primary outcomes

1

Description
GABA amino butyric acid
Timepoint
At the beginning of the study (before the intervention) and 60 days after starting the drug
Method of measurement
High-performance liquid chromatography

2

Description
Dopamine
Timepoint
At the beginning of the study (before the intervention) and 60 days after starting the drug
Method of measurement
High-performance liquid chromatography

3

Description
Serotonin
Timepoint
At the beginning of the study (before the intervention) and 60 days after starting the drug

Method of measurement
High-performance liquid chromatography

4

Description
Glutamate
Timepoint
At the beginning of the study (before the intervention) and 60 days after starting the drug
Method of measurement
High-performance liquid chromatography

Secondary outcomes

1

Description
Improving patient memory and slowing the progression of patient perceptual defects
Timepoint
60 days after starting Berberine supplementation
Method of measurement
Questionnaire for scores of clinical change assessment (CGI) and psychiatric grading criteria (BpRS)

Intervention groups

1

Description
Intervention group: Berberine is a herbal supplement, in the form of a capsule, with a dose of 300 mg, given three times a day for two months for patients with dementia. Medication should be taken after a meal. The number in each package is 30 capsules and the country of manufacture of Iran is Omid Parsina Damavand Company.
Category
Treatment - Drugs

2

Description
Control group: Healthy people without receiving treatment protocols
Category
Diagnosis

3

Description
Control group:The composition of 300 mg of starch, in the form of capsules, is consumed three times a day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Bahram Movahedi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Fasa University of Medical 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
Fasa University of Medical Sciences

Full name of responsible person
Hamidreza Rahmani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Individual data of study participants in accordance with the principle of confidentiality, informed consent form, protocol and how to conduct the study, part of the information obtained based on changes in the initial consequences
When the data will become available and for how long
12 months after receiving permission from IRCT Center
To whom data/document is available
Only researchers working in educational, research and treatment centers affiliated to the Ministry of Health of the Islamic Republic of Iran
Under which criteria data/document could be used
Only in order to implement the research stages of research projects and also necessarily mention the research center of this study (Fasa University of Medical Sciences)
From where data/document is obtainable
Hamidreza Rahmani, Email Address: h.rahmani@fums.ac.ir, Contact Number: 09036016381, Address: Biochemistry Department, Fasa University of Medical Sciences, Ibn Sina Square
What processes are involved for a request to access data/document
1. Sending a request to the IRCT Center and then contacting the respondent scientifically or publicly of the study. 2. Sending a formal and written request to the respondent in the study. 3. Referral of the request to the Vice Chancellor for Research of that university. Ethics is provided to the applicant. 5. The total process time is 20 days.
Comments