

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of Memantine on cognitive impairment in patients with brain tumor under radiotherapy

Protocol summary

Study aim

Determining the effect of memantine on neurological disorders in patients with brain tumors undergoing radiotherapy

Design

In this phase 3 study, a double-blind randomized clinical trial of 70 radiotherapy candidate patients was randomly divided into two groups of 35: memantine and placebo.

Settings and conduct

This study was performed in 2022 in Seyed Al-Shohada Hospital in Isfahan. In this study, patients and the person evaluating the outcome of treatment are unaware of the type of medication received by patients.

Participants/Inclusion and exclusion criteria

In this study, patients with brain tumors who have undergone radiotherapy and have no history of neurological disorders are included in the study.

Intervention groups

70 patients with brain tumors and candidate for radiotherapy are divided into two groups of 35. In the first group, two 5 mg Memantine tablets are given daily 12 hours after a meal and in the control group, placebo tablets are prescribed at the same dose and time. Drug and placebo use in all patients lasts up to 6 weeks

Main outcome variables

Cognitive impairment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211029052903N1**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Susan Andalibi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3233 7964

Email address

susan.andalibi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Memantine on cognitive impairment in patients with brain tumor under radiotherapy

Public title

Evaluation of the effect of Memantine in patients with brain tumors

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with a brain tumor Candidate for radiotherapy
Satisfaction to participate in the study

Exclusion criteria:
Drug allergy to memantine History of neurological disorders

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of patients in two groups is done by simple random method. In this method, the letter I is written on 35 cards and the letter C is written on 35 sheets. All cards are placed in a box and mixed well. When each person enters the study, a card is taken out of the box. According to the letter recorded on the sheet, the patient is assigned to one of the two groups I (intervention) and C (control).

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and the outcome assessor are unaware of the type of medication they are receiving. The medicine and placebo are prepared in similar and coded packages and are given to the patients by the research doctor, but the person who evaluates the outcome of the treatment is unaware of the type of medicine received.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Khoram street
City
Isfahan
Province
Isfahan
Postal code
8434193474

Approval date
2018-05-22, 1397/03/01
Ethics committee reference number
IR.MUI.MED.REC.1397.320

Health conditions studied

1

Description of health condition studied
Cognitive Impairment
ICD-10 code
G31.84
ICD-10 code description
Mild cognitive impairment, so stated

Primary outcomes

1

Description
Cognitive Impariment
Timepoint
Before and 6 weeks after the start of the intervention
Method of measurement
Mini-Mental State Exam(MMSE)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily intake of two 5 mg memantine tablets 12 hours after a meal for 6 weeks
Category
Treatment - Drugs

2

Description
Control group: Receiver of a placebo pill similar to Memantine at the same dose and time as the intervention group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyedoshohada hospital
Full name of responsible person
Susan Andalibi
Street address
Khoram street
City

Isfahan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash
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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

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Simin Hemati
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work

Radiotherapy
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
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Hamid Emami
Position
Associate professor
Latest degree
Specialist
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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ali Mehrabi
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statistical Consultant
Latest degree
Master
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The plan belongs to a government agency and cannot be shared

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available