# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**
Isfehan

**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

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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
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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
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Simin Hemati
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## Person responsible for updating data

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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