Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Evaluation of Amantadine efficacy compared to placebo in the treatment of cancer-related fatigue: a randomized, double-blind clinical trial.

Protocol summary

Study aim
Determining the effectiveness of amantadine compared to placebo in the treatment of cancer-related fatigue

Design
Control-controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 40 patients. The the block random allocation method was used for randomization.

Settings and conduct
This project was carried out at Shahid Sadoughi Hospital in Yazd. Patients in two groups of 20 use amantadine capsule or placebo twice daily for 6 weeks

Participants/Inclusion and exclusion criteria
Inclusion criteria: Cancer patients who complain of fatigue as a side effect of treatment, Patients currently on a chemotherapy regimen are at risk for fatigue Exclusion criteria: Patients with a hemoglobin level of less than 10 g / dl. Patients with a white blood cell count of less than 3,000 cells / mcl. Patients with a platelet count less than 10,000 cells / mcl. Patients with a serum creatinine greater than 2 mg / dl. Patients whose bilirubin level is 1.5 times normal and their alkaline. phosphatase and SGOT levels are more than 3 times normal. Patients with melanoma.

Intervention groups
In order to evaluate the effectiveness of amantadine in cancer fatigue, a group of 20 people is given amantadine and a group of 20 people is given a placebo.

Main outcome variables
Fatigue intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181208041882N10**
Registration date: **2023-10-10, 1402/07/18**
Registration timing: **retrospective**
Last update: **2023-10-10, 1402/07/18**
Update count: **0**

Registration date
2023-10-10, 1402/07/18

Registrant information

Name
behrooz heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 8699

Email address
b.heydari@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-09, 1401/02/19

Expected recruitment end date
2022-08-21, 1401/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Amantadine efficacy compared to placebo in the treatment of cancer-related fatigue: a randomized, double-blind clinical trial.

Public title
Amantadine in cancer fatigue

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cancer patients who complain of fatigue as a side effect of treatment Patients currently on a chemotherapy regimen are at risk for fatigue

Exclusion criteria:

Patients with a hemoglobin level of less than 10 g / dl Patients with a white blood cell count of less than 3,000 cells / mcl Patients with a platelet count less than 10,000 cells / mcl Patients with a serum creatinine greater than 2 mg / dl Patients whose bilirubin level is 1.5 times normal and their alkaline phosphatase and SGOT levels are more than 3 times normal Patients with melanoma

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 40 patients were randomly divided into two treatment groups (A and B). In order to randomize, the block random allocation method was used, in which 10 blocks of 4 were considered. The letters A and B. These permutations were generated with the help of Random software distribution software version 1. For this purpose, the list prepared by software No. 1 to 40 is in 10 blocks of four in general to implement this I want the software output to the first eligible person number 1 and I want to select the last person number 40.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients, the clinical caregiver and the outcome assessor were not aware of the type of medication the patients received. The patients in the two groups received the medications in the same packaging.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine- Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Science, Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2018-02-19, 1396/11/30

Ethics committee reference number

IR.SSU.MEDICINE.REC.1396.197

Health conditions studied

1

Description of health condition studied

Fatigue due to cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Evaluation of fatigue severity

Timepoint

Weeks 0, 1, 2, 3, 4, 5 and 6

Method of measurement

Questionnaire (Cancer-Related Fatigue Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Cancer patients use amantadine hydrochloride 100 mg capsules(Amin company) orally twice a day for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Cancer patients use placebo capsules twice a day for 6 weeks. Amantadine placebo is made using capsule pumice purchased from Amin company and by capsule filling machine using cellulose powder.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi hospital

Full name of responsible person
Hasanali vahedian

Street address
Ibn Sina Street, Shahid Ghandi Boulevard, Safaieh, Yazd.

City
Yazd

Province
Yazd

Postal code
۸۹۱۵۸۸۷۸۵۷

Phone
+98 35 3822 4000

Email
sadoghi-hospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
امیرهوشنگ مهرپرور

Street address
Shahid Sadoughi University of medical sciences, Shohadaye Gomnan Blvd, Alem Sq

City
Yazd

Province
Yazd

Postal code
8915173149

Phone
+98 35 3146 2150

Email
ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Behrooz Heydari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam Blvd, Alem Sq

City
Yazd

Province
Yazd

Postal code
8915173143

Phone
+98 35 3820 3410

Email
b.heydari@ssu.ac.ir

Person responsible for scientific inquiries

Contact

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Yazd University of Medical Sciences

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Phone
+98 35 3820 3410

Email
b.heydari@ssu.ac.ir

Person responsible for updating data

Contact

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Yazd University of Medical Sciences

Full name of responsible person
Behrooz Heydari
Position
Assistant professor
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Shahid Sadoughi University of medical sciences, Shohadaye Gomnam Blvd, Alem Sq
City
Yazd
Province
Yazd
Postal code
8915173143
Phone
+98 35 3820 3410
Email
b.heydari@ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
After nonrecognition, all data can be share
When the data will become available and for how long
6 months after publication
To whom data/document is available
All of researchers
Under which criteria data/document could be used
nothing
From where data/document is obtainable
Behrooz Heydari email: b.heydari@ssu.ac.ir
What processes are involved for a request to access data/document
Request your information by email. The data will be sent after a week.
Comments