Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Study of the efficacy of memantine as adjunctive therapy with chemotherapy regimen in metastatic colon cancer: A pilot randomized clinical trial

Protocol summary

Study aim
Determining the anti-cancer effects of memantine in colon cancer

Design
Clinical trial with control group and intervention group, double-blind, randomized, phase 2 on 50 patients. Block randomization method will be performed according to the corresponding sample size.

Settings and conduct
In this study, patients over 18 years of age with metastatic colorectal cancer referred to the subspecialty blood and oncology clinic of Imam Khomeini Hospital in Urmia who was newly diagnosed were used. After receiving conscious consent to enter the study the patients were randomly divided into two groups of 25 people equal to the standard drug treatment regimen plus memantine and the standard drug control group (control). According to the usual routine for all patients in the clinic the information about age, sex, pathology of the disease, CT scan report of the patient and concomitant diseases and initial tests will be included in the file in all patients. In patients in the first group, in addition to standard chemotherapy regimen the memantine at a dose of 20 mg per day for 3 months (starting with a daily dose of 5 mg and adding 5 mg per week and up to a maximum dose of 20 mg) was administered. The second group will be given a standard chemotherapy regimen without memantine.

Participants/Inclusion and exclusion criteria
All patients over 18 years of age with metastatic colon cancer that don't have severe renal failure (29-mL / min (CLcr 15 -), liver failure (more than 5-fold increase in liver enzymes), history of memantine allergy, history of seizures, cardiovascular disease, eye disease, and concomitant use of drugs that alter the pH of the urine.

Intervention groups
two equal groups of 25 people with standard drug therapy regimen plus memantine and standard drug control group (control).

Main outcome variables
quality of life; BMI; VEGF; CEA; size of tumor

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210819052230N1**
Registration date: **2022-01-29, 1400/11/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-29, 1400/11/09**
Update count: **0**

Registration date
2022-01-29, 1400/11/09

Registrant information

Name
Hamid Soraya

Name of organization / entity

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Iran (Islamic Republic of)

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+98 44 3275 4996

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-10, 1400/10/20

Expected recruitment end date
2022-04-09, 1401/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the efficacy of memantine as adjunctive therapy with chemotherapy regimen in metastatic colon cancer: A pilot randomized clinical trial

Public title

Study of the efficacy of memantine in metastatic colon cance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients over 18 years of age with metastatic colon cancer

Exclusion criteria:

Severe renal failure Liver failure (more than 5-fold increase in liver enzymes) History of memantine allergy History of seizures Cardiovascular disease Eye diseases Concomitant use of drugs that alter the pH of the urine.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, which will be allocated to 25 people in each group in a block plan, first, because there are two groups A and B, there will be 25 groups of 2, with group A being the intervention group and group B being the control group. After determining the cases, 25 cases will be selected using a random number table, and after determining the order, the list of patients will be randomly divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, an epidemiologist colleague will randomly divide patients into two groups, and the physician will prescribe medication for the intervention group. The participants, researcher, and data analyst are blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Pardis Nazlou, 11 km of Nazlou Road,Urmia,Iran

City

Urmia

Province

West Azarbaijan

Postal code

5756115327

Approval date

2021-11-13, 1400/08/22

Ethics committee reference number

IR.UMSU.REC.1400.302

Health conditions studied

1

Description of health condition studied

Metastatic colon cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

Primary outcomes

1

Description

Quality of life in patient with colon cancer

Timepoint

Beginning and end of the study (third month)

Method of measurement

QLQ-C30 Questionnaire

2

Description

The size of tumor in patients with colon cancer

Timepoint

Beginning and end of the study (third month)

Method of measurement

CT scan

Secondary outcomes

1

Description

Vascular endothelial growth factor (VEGF)

Timepoint
Beginning and end of the study (third month)
Method of measurement
ELISA kit

2

Description
Carcinoembryonic Antigen (CEA)
Timepoint
Beginning and end of the study (third month)
Method of measurement
ELISA kit

3

Description
Body Mass Index (BMI)
Timepoint
Beginning and end of the study (third month)
Method of measurement
weight kg/height m2

Intervention groups

1

Description
Intervention group: Standard chemotherapy drugs for colon cancer + memantine Memantine, which is our intervention, will be administered orally at a dose of 20 mg per day. Thus, in the first week, 5 mg daily and then 5 mg per week will be added and eventually continued at a dose of 20 mg per day for three months.
Category
Treatment - Drugs

2

Description
Control group: Standard chemotherapy drugs for colon cancer without prescribing memantine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Blood and Oncology Clinic of Imam Khomeini Hospital in Urmia
Full name of responsible person
Hamid Soraya and Rahim Asghari
Street address
Imam Khomeini University Hospital-Ershad Ave-Modarres Blvd-Urmia-Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
University Campus: Pardis Nazlou, 11 km of Nazlou Road,Urmia,Iran
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Hamid Soraya
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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