

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Studying of Black Seed effect as a complementary chemotherapy treatment on biomarkers of patients with colorectal cancer

Protocol summary

Study aim

Assessment of Black Seed effect on the biomarkers of patients with colorectal cancer.

Design

The study is done in Phase 2 clinical trials without a control group, with a single group, without blinding. Patients with colorectal cancer who have performed colon surgery and they are in stage IIb and III colon cancer, participated in this study. 18 patients participate in this study.

Settings and conduct

A study is conducted at Qom Shahid Beheshti Hospital. Patients with colorectal cancer who have undergone colon surgery are included in this study of 18 people in a sample group. Serum bio-markers will be evaluated at the baseline, 3 months following the treatment and the end of treatment due to investigation on probable effect of black seed capsule on decreasing bio-markers level.

Participants/Inclusion and exclusion criteria

entrance condition: Age between 20 and 70 years and achieving the first time chemical therapy after colorectal cancer surgery. non entrance condition: Pregnant and lactating women.

Intervention groups

Black seed capsule

Main outcome variables

cancer antigen 19-9 (CA19-9); Carcino Embryonic Antigen (CEA)

General information

Reason for update

Due to the duration of treatment, multiplicity and side effects of chemotherapy drugs in patients with colorectal cancer included in the present study, many patients were excluded from the study and did not want to continue treatment. Therefore, due to the fact that in colorectal cancer, patients' tumor markers are examined and followed up, this study was performed as a clinical

trial without blinding. Also, due to the fact that the dose of black seed capsule per day is 1000 mg and this amount is allowed in all temperaments, so the use of temperament questionnaire was not done in patients.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180513039641N1**

Registration date: **2018-08-29, 1397/06/07**

Registration timing: **prospective**

Last update: **2025-05-03, 1404/02/13**

Update count: **2**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Hoda Abolhasani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3320 9071

Email address

habolhasani@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

2018-11-06, 1397/08/15

Actual recruitment end date

2020-03-15, 1398/12/25

Trial completion date

2020-11-02, 1399/08/12

Scientific title

Studying of Black Seed effect as a complementary chemotherapy treatment on biomarkers of patients with colorectal cancer

Public title

Studying of Black Seed effect on colorectal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 70 years Patients who are aware of their colorectal cancer disease Performing colorectal cancer Surgery The existence of colorectal cancer-Stage IIb and III The first time achieving chemical therapy after colorectal cancer surgery

Exclusion criteria:

Pregnant and lactating women and married women in childbearing age who do not use reliable contraceptive methods

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **18**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research of Qom
University of Medical Sciences

Street address

No. 83, Alley No. 4, Alley 1/1, Safashahr Street

City

Qom

Province

Ghous

Postal code

3716987366

Approval date

2018-05-01, 1397/02/11

Ethics committee reference number

IR.MUQ.REC.1397.015

Health conditions studied

1

Description of health condition studied

Colorectal cancer

ICD-10 code

C19

ICD-10 code description

Malignant neoplasm of rectosigmoid junction

2

Description of health condition studied

colon cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

3

Description of health condition studied

rectum cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes

1

Description

cancer antigen 19-9 (CA19-9)

Timepoint

Baseline, 3 months following the treatment and the end of treatment

Method of measurement

Blood test

2

Description

Carcino Embryonic Antigen (CEA)

Timepoint

Baseline, 3 months following the treatment and the end of treatment

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Black seed capsule (containing fresh black seed powder) in the amount of 1000 mg three times a day (it is better to take black seed capsule 2 hours before or 2 hours after a meal).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Beheshti Medical Education Center

Full name of responsible person

Talieh Mollabashi

Street address

Shaheed Beheshti Blvd

City

Ghous

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2000

Fax

+98 25 3612 2855

Email

dr.talieh918@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Hosein Saghafi

Street address

No. 83, Alley 4, Alley 1/1, Safashahr St.

City

Ghous

Province

Ghous

Postal code

3716987366

Phone

+98 25 3285 2720

Fax

+98 25 3285 8464

Email

dr.hosseinsaghafi@gmail.com

Web page address

<http://res.muq.ac.ir/index.aspx>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Hoda Abolhasani

Position

Assistance Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medicinal Chemistry

Street address

Pharmacology group, medicin faculty, Ghous pardis university of medical sciences

City

Ghous

Province

Ghous

Postal code

3716987366

Phone

+98 25 3320 9071

Email

hodaabolhasani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Davoud Ouladdamesghi

Position

Assistance Professor

Latest degree

Subspecialist

Other areas of specialty/work

Oncology

Street address

Shaheed Beheshti Blvd

City

Ghoum
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2000
Email
dodameshghi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Hoda Abolhasani
Position
Assistance Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medicinal Chemistry
Street address
Pharmacology group, medicin faculty, Ghoum pardis
university of medical sciences
City
Ghoum
Province
Ghoum
Postal code
3716985598
Phone
+98 25 3320 9071
Email

hodaabolhasani@gmail.com

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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

After receiving the results of the study, there are plans to publish the article in valid journals

When the data will become available and for how long

all the time

To whom data/document is available

Depending on the journal in which the study is published

Under which criteria data/document could be used

After receiving the results of the study, there are plans to publish the article in valid journals

From where data/document is obtainable

Depending on the journal in which the study is published

What processes are involved for a request to access data/document

Depending on the journal in which the study is published

Comments