

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Determination of Rheum ribes L. aqueous extract effect on FOLFOX-induced neuropathy in patients with Colorectal Cancer

Protocol summary

Study aim

evaluate the efficacy of aqueous extract of Rheum ribes L. on FOLFOX-induced neuropathy in patients with Colorectal Cancer.

Design

This study is a randomized, double blind, placebo controlled trial conducted on 44 patients.

Settings and conduct

This study will be conducted multi centrally in Imam Khomeini Hospitals of Tehran, Shah Wali in Yazd, Yasrebi in Kashan and Baghiatallah of Qom

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Colorectal Cancer, aged between 20 and 80 years old, receiving the FOLFOX chemotherapy regimen Exclusion criteria: patients with a history of other types of cancers, history of receiving chemotherapy, history of seizure and drug use anticonvulsants, previous neuropathy, having allergies and allergic to each of the components studied.

Intervention groups

The intervention group will be received required medications and 5 cc aqueous extract of rhubarb daily for seven days .This process continue until the seventh course of chemotherapy. The intervention group will be received required medications and 5 cc placebo daily for seven days .This process continue until the seventh course of chemotherapy

Main outcome variables

the sensitivity touching cold hyperalgesia the severity of neuropathy experiencing tingling in hands or feet

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140817018828N4**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **retrospective**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Alimohammad Ranjbar

Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3419

Email address

amranjbar@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2017-09-22, 1396/06/31

Trial completion date

empty

Scientific title

Determination of Rheum ribes L. aqueous extract effect on FOLFOX-induced neuropathy in patients with Colorectal Cancer

Public title

Evaluation of Rheum ribes L. aqueous extract effect on neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Colorectal Cancer aged between 20 and 80 years old receiving the FOLFOX chemotherapy regimen

Exclusion criteria:

patients with a history of other types of cancers history of receiving chemotherapy history of seizure and drug use anticonvulsants previous neuropathy having allergies and allergic to each of the components studied

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Double blind

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yazd University of Medical Sciences

Street address

Bahonar square

City

Yazd

Province

Yazd

Postal code

8917693571

Approval date

2016-07-16, 1395/04/26

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

colorectal cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

Primary outcomes**1****Description**

. Peripheral neuropathy

Timepoint

End of day 7 after each chemotherapy course until the seventh term of chemotherapy

Method of measurement

questionnaire

Secondary outcomes**1****Description**

the sensitivity touching cold

Timepoint

End of day 7 after each chemotherapy course until the seventh term of chemotherapy

Method of measurement

questionnaire

2**Description**

hyperalgesia

Timepoint

End of day 7 after each chemotherapy course until the seventh term of chemotherapy

Method of measurement

questionnaire

3**Description**

experiencing tingling in hands or feet

Timepoint

End of day 7 after each chemotherapy course until the seventh term of chemotherapy

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Patients randomly enter the intervention group, and use 5 ml of the prescribed extract for 7 days from the second day of chemotherapy until the seventh course of chemotherapy

Category

Treatment - Drugs

2

Description

Control group: Patients randomly enter the control group, and use 5 ml of the placebo for 7 days from the second day of chemotherapy until the seventh course of chemotherapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Fatemeh Ghotbinejad

Street address

Farmer Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

Ghotbi_fat90@yahoo.com

2

Recruitment center

Name of recruitment center

Baghiatallah Hospital

Full name of responsible person

Fatemeh Ghotbinejad

Street address

Vanak Square

City

Qom

Province

Ghous

Postal code

1435915371

Phone

+98 25 8805 0436

Email

Ghotbi_fat90@yahoo.com

3

Recruitment center

Name of recruitment center

Shah Vali hospital

Full name of responsible person

Fatemeh Ghotbinejad

Street address

Professor Hessabi Street

City

Yazd

Province

Yazd

Postal code

8916871967

Phone

+98 35 3821 1091

Email

Ghotbi_fat90@yahoo.com

Web page address

4

Recruitment center

Name of recruitment center

Yasrebi Hospital

Full name of responsible person

Fatemeh Ghotbinejad

Street address

Ghotb-e- Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

88715973474

Phone

+98 31 5562 1530

Email

Ghotbi_fat90@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Hooshang Mehrparvar

Street address

Bahonar Square

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3724 0171

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

Alimohamad Ranjbar Jamal abadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Professor Hesabi Boolvar

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3820 3865

Email

Amranjbar@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Alimohamad Ranjbar Jamal abadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Professor Hesabi Boolvar

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3820 3865

Email

Amranjbar@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Ghotbinejad

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Professor Hesabi Boolvar,

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3728 0215

Email

Ghotbi_fat90@yahoo.com

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