

# 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