

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Determination of Apium graveolens L.fruit effect on folfox induced neuropathy in patient with colorectal cancer.

#### Protocol summary

##### Summary

The present study is double-blinded intervention and clinical trial which is aimed at investigating the effects of Apium graveolens L.fruit on neuropathy resulted from chemotherapy with folfox in patients with colorectal cancer. 66 patients within the range of 20 to 80 years old were selected and were randomly divided into two groups. The patients were included in the study upon their own satisfaction and according to study entrance and exit criteria and normality of monofilament test so that we made sure they were not suffering from neuropathy. Patients in main group received standardized capsules containing in Apium graveolens L.fruit for 12 courses daily with 8h spans. They were informed of consumption instructions and time. Patients were closely observed in each of the twelve courses. The control group, on the other hand, underwent the same process except that the capsules received by the patients in this group contained cellulose. Finally the results were compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017030818828N2**

Registration date: **2017-04-18, 1396/01/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-04-18, 1396/01/29

##### 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

Yazd University of Medical Sciences

###### Expected recruitment start date

2017-04-21, 1396/02/01

###### Expected recruitment end date

2017-07-23, 1396/05/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Determination of Apium graveolens L.fruit effect on folfox induced neuropathy in patient with colorectal cancer.

###### Public title

Determination of Apium graveolens L.fruit effect in patient with colorectal cancer.

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Patient must be suffering from colorectal cancer; Patient must be between 20 to 80 years old; The patient must have received folfox diet containing folinic acid; 5-fluoro uracil and oxaliplatin; Full satisfaction of the patient Exclusion criteria: Patients who take acupuncture during their treatment; Patients who receive massage therapy during their treatment; Patients who receive physiotherapy during their treatment;

Patients who take indigenous medicine; Patients with previously-diagnosed neuropathy; Patients with lupus or rheumatoid arthritis; Patients with other forms of cancer

#### **Age**

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

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **66**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Yazd University of Medical Sciences

###### **Street address**

Talar honar alley, Bahonar square, Yazd, Iran

###### **City**

Yazd

###### **Postal code**

8917693571

###### **Approval date**

2010-09-23, 1389/07/01

###### **Ethics committee reference number**

IR.SSU.REC.1395.69

### **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**

The pain

##### **Timepoint**

Before treatment, 5 to 6 months after treatment

##### **Method of measurement**

Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Patients in main group received standardized capsules containing in Apium graveolens L.fruit for 12 courses daily with 8h spans. They were informed of consumption instructions and time. Patients were closely observed in each of the twelve courses.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Patients in main group received standardized capsules containing in cellulose for 12 courses daily with 8h spans. They were informed of consumption instructions and time.

##### **Category**

Placebo

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Yazd University of Medical Sciences

###### **Full name of responsible person**

Masoud Kalami Yazdi

###### **Street address**

Yazd, Iran

###### **City**

Yazd

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Yazd University of Medical Science

###### **Full name of responsible person**

Hooshang Mehrparvar

###### **Street address**

Bahonar Square, Yazd, Iran

###### **City**

Yazd

**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 Science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**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**

PhD

**Other areas of specialty/work**

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Mohamadreza Mortazavizadeh

**Position**

Oncologist, Assistant Professor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

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Yazd University of Medical Science

**Full name of responsible person**

Amir Mohammad Safavi

**Position**

Student Doctor of Pharmacy

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*