

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)

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+98 35 3820 3419

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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

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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

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Position

PhD

Other areas of specialty/work

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Person responsible for scientific inquiries

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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