

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of omega-3 on cancer related fatigue in cancer patients and its comparison with the control group

Protocol summary

Study aim

The aim of this study was to evaluate the effect of omega-3 supplementation on cancer-related fatigue in cancer patients under chemotherapy and compare it with the effect of Ginseng on it.

Design

Clinical trials with control group with randomized, multifaceted, randomized, randomized groups

Settings and conduct

In the study of the effect of pharmacological interventions on cancer-related fatigue in chemotherapy clinics affiliated to Isfahan University of Medical Sciences

Participants/Inclusion and exclusion criteria

Entry requirements: Age 30 to 60 years, and lack of supplementation of omega-3 in the past 3 months and cancer-related fatigue during chemotherapy.

Intervention groups

Usage of omega-3 supplementation in intervention group and Ginseng consumption in control group

Main outcome variables

The main consequences are the improvement of various parameters of weakness including physical fatigue and ...in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170308032957N2**

Registration date: **2018-05-16, 1397/02/26**

Registration timing: **retrospective**

Last update: **2018-05-16, 1397/02/26**

Update count: **0**

Registration date

2018-05-16, 1397/02/26

Registrant information

Name

mohammad nouranian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3274 2542

Email address

m_nouranian@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 on cancer related fatigue in cancer patients and its comparison with the control group

Public title

The effect of omega-3 on cancer related fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 30 to 60 years for participants Have definite diagnosis of cancer and indicate chemotherapy or undergo chemotherapy Cancer related fatigue in patients

with a score of 40 and above in the questionnaire Ability to read and write by patients Ability to eat an oral medication by patients Lack of supplementation of omega-3 in the last 3 months Insensitivity to fish Lack of use of anticoagulants(except aspirin) Insensitivity to soy Lack of anemia Satisfaction of patients to participate in the study

Exclusion criteria:
Patient's death during the study Having a disease that is not able to participate in the study more than 20% of the questionnaire has not been completed

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by simple randomization method and generating random values between zero and one in the spss software. To assign random values to the intervention or control group using the lottery, values less than or equal to 0.5 are assigned to group A and values greater than 0.5 are assigned to group B. Then, by a person independent of the research team code 70 envelopes (based on the codes obtained in the above randomization method) and a list of codes is specified. In the envelope, based on the above method, a new treatment or standard treatment (conventional) will be written and, according to the entry of eligible patients, will be given to patients in the clinic to give an oncologist. The therapist provides the necessary prescriptions based on the groupings done for each patient. In the meantime, the researcher does not know which patient, in which group A or B, is.

Blinding (investigator's opinion)
Double blinded

Blinding description
The secretary introduced the patients to the oncologist using a randomized grouping and the oncologist provided treatments for both groups according to the grouping done. The investigator, in collaboration with the oncologist, supervised the patient's use of the drug. After collecting the questionnaire data was completed by the patients, the data was analyzed by a statistician specialist with respect to the confidentiality of the grouping.

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Science

Street address

Isfahan Hezar jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-05-17, 1396/02/27

Ethics committee reference number

IR.MUI.REC.1396.3.182 396182

2

Ethics committee

Name of ethics committee

Isfahan University of Medical Science

Street address

Hezaar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-02-17, 1395/11/29

Ethics committee reference number

396182

Health conditions studied

1

Description of health condition studied

cancer related fatigue

ICD-10 code

R53.0

ICD-10 code description

Neoplastic (malignant) related fatigue

Primary outcomes

1

Description

cancer related fatigue
Timepoint
zero- 3 weeks-6 weeks
Method of measurement
multi variable Questionnaire

Secondary outcomes

1

Description
adherence to treatment
Timepoint
zero-3 weeks-6 weeks
Method of measurement
Questionnaire(Morisky)

Intervention groups

1

Description
Intervention group: In this group, patients receive 4 capsules each day of 250 mg of Ginseng capsule, which has Ginsin brand name and owned by the Iranian pharmaceutical company GOL DAROU, for 3 weeks and discontinues the drug for one week and re-use it for another 3 weeks (standard treatment). In addition, during this period, patients receive a capsule of 1 gram of omega-3 daily from the Australian Pharmaceutical Company GMV with a health certificate of 70009004710001 with the main meal for 6 weeks (new treatment).
Category
Treatment - Drugs

2

Description
control group: In this group, patients receive 4 capsules each day of 250 mg of Ginseng capsule, which has Ginsin brand name and owned by the Iranian pharmaceutical company GOL DAROU, for 3 weeks and discontinues the drug for one week and re-use it for another 3 weeks (standard treatment). The duration of the drug is 6 weeks in total.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra clinics
Full name of responsible person
Ali Hajigholami
Street address
Sheikh Mofid Street
City
Isfahan

Province
Isfahan
Postal code
8163743787
Email
Ali_hajigholami@yahoo.com

2

Recruitment center
Name of recruitment center
Alzahra clinics
Full name of responsible person
Ali Hajigholami
Street address
Sheikh Mofid Street
City
ISFAHAN
Province
Isfahan
Postal code
8163743787
Email
Ali_hajigholami@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Tel:03137928139 Mrs Shaghayegh Haghjooye Javaanmard
Street address
Hezar Jarib Street-Vice Chancellery of Research and Technology
City
Isfahan
Province
Isfahan
Postal code
8174673461
Email
Ali_hajigholami@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
Department of Social and Family Medicine
Full name of responsible person
Mohammad Nouranian
Position
Family Medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
Family Physician
Street address
Department of Social Medicine, Isfahan University of
Medical Sciences
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 8123
Fax
Email
Mohamednouranianmn7@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Department of Social Medicine, Isfahan University of
Medical Sciences
Full name of responsible person
Dr Houriyeh Ansari
Position
Social Medicine Specialist
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Department of Social and Family Medicine
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 8123
Fax
Email
hourijansari@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Department of Social and Family Medicine, Isfahan
University of Medical Sciences
Full name of responsible person
Dr Mohammad Nouranian
Position
Family Medicine Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Street address
Department of Social and Family Medicine
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3273 2542
Fax
Email
mohamed.nouranian@gmail.com
Web page address

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

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data in the study except for personal data can be shared.

When the data will become available and for how long

The start of the access period is 6 months after the results are printed.

To whom data/document is available

At the current stage, the results will be available to researchers at university institutes.

Under which criteria data/document could be used

In terms of data analysis and analysis for academic researchers and use in later studies.

From where data/document is obtainable

School of social medicine, Isfahan
Ali_hajigholami@yahoo.com

What processes are involved for a request to access

data/document

By submitting a written request to the director of the

Social Medicine School, Isfahan

Comments