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
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Iran (Islamic Republic of)
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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

Isfehan

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

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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

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Recruitment center

Name of recruitment center

Alzahra clinics

Full name of responsible person

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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

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Hezar Jarib Street-Vice Chancellery of Research and Technology

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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 rezident
Latest degree
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Person responsible for updating data

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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