

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effects of omega-3 fatty acids on oxaliplatin-induced neuropathy and inflammation in patients with colon cancer

Protocol summary

Summary

Oxaliplatin (OXL) is used in the treatment of colorectal cancer. Peripheral neuropathy is one of the most common dose-limiting toxicity of OXL which impair significantly the patients' quality of life. Inflammatory cytokines induce inflammatory and neuropathic pain and hyper excitability by their direct and indirect effect on central and peripheral neurons and they are risk factors for the development of PN. Omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) have many beneficial effects in the psychiatric and neurodegenerative diseases and attenuated the production of pro inflammatory cytokines. The aim of this study is to evaluate the possible effects of omega-3 fatty acid supplementation on OXL-induced peripheral neuropathy (OXIPN) in patients with colon cancer. 60 patients with colon cancer candidate for receiving Oxaliplatin are being included in the study and those who are suffering from the diseases associated with neuropathy (e.g. diabetes and primary neural diseases); having history of previous chemotherapy and receiving any forms of supplementation (fish oil, vitamins & minerals) since 3 months before enrollment excluded from the study. They will be randomly assigned in a 1:1 ratio to receive oil fish pearls or placebo 3 times a day during the chemotherapy with oxaliplatin and one month after the end of the treatment. Incidence and severity of OXIPN (by TNSr), Nerve conduction study (NCS) and serum levels of pro inflammatory cytokines, IL-1 β , TNF- α and IL-6 and highly sensitive C reactive protein (hs-CRP), are assessed before treatment with oxaliplatin and at one month after the cessation of the treatment. To our knowledge, the evaluation of possible effects of omega-3 fatty acid supplementation on OXL-induced PN in patients with colon cancer was not studied before

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112158397N2**

Registration date: **2011-12-24, 1390/10/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-12-24, 1390/10/03

Registrant information

Name

Ali Esfahani

Name of organization / entity

Tabriz University of Medical Sciences, Hematology
Oncology Reseach Center

Country

Iran (Islamic Republic of)

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+98 41 1333 1712

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Recruitment status

Recruitment complete

Funding source

Liver and Gastrointestinal Diseases Research
Center, Tabriz University of Medical Sciences; IRAN Sanofi
Aventis Group

Expected recruitment start date

2012-02-02, 1390/11/13

Expected recruitment end date

2013-08-02, 1392/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of omega-3 fatty acids on oxaliplatin-induced neuropathy and inflammation in patients with colon cancer

Public title

Omega-3 fatty acids and chemotherapy-induced neurotoxicity in colon cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterion: Patients with colorectal cancer (high risk stage 2, stage 3 & 4) candidate to receive oxaliplatin. Exclusion criteria: Suffering from the diseases associated with neuropathy (e.g.diabetes, and primary neural diseases); any previous chemotherapy and receiving any forms of supplementation (fish oil, vitamins &minerals) since 3 months before enrollment

Age

From **20 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethical Committee of Tabriz University of Medical Sciences

Street address

Research Deputy-Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2010-10-18, 1389/07/26

Ethics committee reference number

5/4/10130

Health conditions studied

1

Description of health condition studied

Colon cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

Primary outcomes

1

Description

Incidence and severity of oxaliplatin-induced peripheral nauopathy

Timepoint

before chemotherapy with oxaliplatin and one month after the end of the treatment

Method of measurement

Reduced total neuropathy score(rTNS) and Electrophysiological evaluation

2

Description

Serum concentration of interleukin-1 beta

Timepoint

before chemotherapy with oxaliplatin and one month after the end of the treatment

Method of measurement

ELISA

3

Description

Serum concentration of interleukin-6

Timepoint

before chemotherapy with oxaliplatin and one month after the end of the treatment

Method of measurement

ELISA

4

Description

Serum concentration of TNF-alpha

Timepoint

before chemotherapy with oxaliplatin and one month after the end of the treatment

Method of measurement

ELISA

5

Description

Serum concentration of Highly sensitive-CRP

Timepoint

before chemotherapy with oxaliplatin and one month after the end of the treatment

Method of measurement

Nephelometry

Secondary outcomes

1

Description

concentrations of omega-3 fatty acids in the serum phospholipids

Timepoint

before chemotherapy with oxaliplatin and one month after the end of the treatment

Method of measurement

Gas chromatography

Intervention groups

1

Description

Intervention: Eligible recruited patients with colorectal cancer who randomly assigned to be in the intervention arm, received 640 mg oil fish pearls (54% DHA and 10% EPA)3 times a day for 6 months during chemotherapy with oxaliplatin

Category

Treatment - Drugs

2

Description

Control: Eligible recruited patients with colorectal cancer who randomly assigned to be in the control arm received placebo pearls 3 times a day for 6 months(during chemotherapy with oxaliplatin)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikhorais Clinic of Tabriz University of Medical Sciences

Full name of responsible person

Ali esfahani

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Liver and Gastrointestinal Diseases Research Center,Tabriz University of Medical Sciences

Full name of responsible person

Mirinejad

Street address

Imam Khomeini Hospital, University Ave

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Liver and Gastrointestinal Diseases Research Center,Tabriz University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Added at 2014-08-27:SANOFI IRAN

Full name of responsible person

Added at 2014-08-27: Lida Zeinali

Street address

No 18, 35th, Alvand Ave., Argentina Square

City

Added at 2014-08-27: Tehran

Grant name

1393/6/5 پروژرسانی: -

Grant code / Reference number

Added at 2014-08-27: -

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Added at 2014-08-27:SANOFI IRAN

Proportion provided by this source

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

Tabriz University of Medical Sciences

Full name of responsible person

Ali Esfahani

Position

Hematologist-Oncologist, Assistant Professor of Tabriz
University of Medical Sciences

Other areas of specialty/work**Street address**

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Zohreh Ghoreishi

Position

Assistant professor of Nutrition Research Center,
Tabriz University of Medical Sciences

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zohreh_ghoreishy@yahoo.com

Web page address**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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hematology-Oncology Research center, Tabriz
University of Medical Sciences

Full name of responsible person

Ali Esfahani

Position

Hematologist-Oncologist, Assistant Professor of Tabriz
University of Medical Sciences

Other areas of specialty/work**Street address**

Shahid Ghazi Hospital, Tabriz University of Medical
Sciences

City

Tabriz

Postal code**Phone**

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