Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-1β, 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

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Name of organization / entity
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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 nauropathy

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

Nephlometry

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
بروزرسانی 1393/6/5: -
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

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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