

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of omega 3 intake on cancer risk factors in smokers

Protocol summary

Summary

Our goal is to investigate reducing the effects of free radicals on biomolecules such as nucleic acids, proteins, and lipids by using omega-3 in smokers. 80 healthy men (40 smokers and 40 nonsmokers) with age of 25 to 50 years old will receive one gram of omega-3 fatty acid (capsules manufactured by Zahravi Pharmaceutical Company) one hour after a meal everyday for a period of three months. Patients with cardiovascular disorders, metabolic disease such as diabetes, cancer, malabsorption disorders, and renal failure are excluded. A person is considered as smoker if he smokes more than 10 cigarettes in a day for 2 years prior to study. Levels of 8OHdG and OX-LDL will be measured before the study and 3 months after the completion of the treatment period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803101267N4**
Registration date: **2009-08-30, 1388/06/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-08-30, 1388/06/08

Registrant information

Name

Mojgan Borgheie

Name of organization / entity

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 7222

Email address

research@unrc.ir

Recruitment status

Recruitment complete

Funding source

Urology and Nephrology Research Center

Expected recruitment start date

2008-12-21, 1387/10/01

Expected recruitment end date

2010-12-21, 1389/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of omega 3 intake on cancer risk factors in smokers

Public title

Effect of omega 3 intake on cancer risk factors in smokers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: male sex, age between 25 and 50 years old
Exclusion criteria: Presence of cardiovascular disorders, metabolic disease such as diabetes, cancer, malabsorption disorders, or renal failure

Age

From **25 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.R.

Street address

UNRC, No.101, 9th Boostan St., Pasdaran Ave.,
Tehran, I.R.Iran

City

Tehran

Postal code

1666677951

Approval date

empty

Ethics committee reference number

93

Health conditions studied

1

Description of health condition studied

Cancer of urinary tract

ICD-10 code

C64, C65,

ICD-10 code description

Malignant neoplasms of urinary tract

Primary outcomes

1

Description

Carbonil level in serum

Timepoint

Baseline and 3 month later

Method of measurement

ELISA

Secondary outcomes

1

Description

OX-LDL level

Timepoint

Baseline and 3 month later

Method of measurement

ELISA

2

Description

8OHdG levels

Timepoint

At first and 3 month later

Method of measurement

ELISA

Intervention groups

1

Description

Omega 3 capsule, 1 gram for 3 month

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.

Full name of responsible person

Shabnam Golshan

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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

Urology and Nephrology Research Center (UNRC), Shahid
Beheshti University, M.C.(SBMU), Tehran, I.

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***City**

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Dr Hassan Argani

Position

Associate Professor

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Dr Mozghan Borgheie

Position

General physician

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Dr Hassan Argani

Position

Associate Professor

Other areas of specialty/work**Street address**Urology and Nephrology Research Center (UNRC),
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Iran**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*