Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the effects of omega-3 fatty acids on Th1/Th2/Th9/Th17/Th22 cytokines in patients with differentiated thyroid cancer under the treatment with radioiodine

Protocol summary

Study aim
Determination of omega-3 effects on 13 cytokines belong to different T cell subsets including Th1/Th2/ Th9 /Th17/Th22 in patients with differentiated thyroid cancer under the treatment with radioiodine

Design
In G2, the first blood sample was collected 1 month before RAI ablation. Then patients started to take omega-3 for 30 days and the second blood sample was collected immediately before RAI ablation. The third and fourth blood samples were collected one week and one month after RAI ablation, respectively. In G1 and G3, blood samples were collected immediately before RAI ablation as well as one week and one month after RAI ablation. Serum was isolated from each blood sample and stored at −20°C. Cytokine assays was done with cytometric bead-based assay.

Settings and conduct
Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria
Adult patients with DTC who had total or near-total thyroidectomy and planned to treat with radioiodine with 100 or 150 mCi

Intervention groups
The patients with DTC were divided into two groups based on RAI dosage: high dose with 150 mCi and intermediate dose with 100 mCi. Then patients in each group was randomly divided into three subgroups: G1 with RAI ablation only, G2 treated with omega-3 for 30 days before RAI ablation, and G3 treated with omega-3 for 30 days after RAI ablation.

Main outcome variables
Cytokine change

General information

Reason for update

Acronym
DTC, RAI

IRCT registration information
IRCT registration number: **IRCT20220104053622N1**
Registration date: **2022-02-05, 1400/11/16**
Registration timing: **retrospective**

Last update: **2022-02-05, 1400/11/16**
Update count: **0**

Registration date
2022-02-05, 1400/11/16

Registrant information

Name
Shirin Farjadian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-09, 1398/11/20

Expected recruitment end date
2021-02-08, 1399/11/20

Actual recruitment start date
2020-02-09, 1398/11/20

Actual recruitment end date
2021-05-10, 1400/02/20

Trial completion date
2021-05-10, 1400/02/20

Scientific title

Investigation of the effects of omega-3 fatty acids on Th1/Th2/Th9/Th17/Th22 cytokines in patients with differentiated thyroid cancer under the treatment with radioiodine

Public title

Investigation of the effects of omega-3 on immune system in patients with thyroid cancer under the treatment with radioiodine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Involving with differentiated thyroid cancer Adult patients Total or near-total thyroidectomy Planned for radioiodine ablation with 150 mCi or 100 mCi

Exclusion criteria:

Patients who will be received radioiodine at doses higher than 150 mCi Patients who were previously received radioiodine Patients who had taken omega-3 or other supplements before the study Patients who had undergone a second thyroid surgery Patients who have other cancers Patients who have concurrent chronic inflammatory disease Patients who have autoimmune disease or other cancers

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **4**

- In G2: The first blood sample was taken one month before RAI. The second sample was taken 30 days after taking omega-3 and just before RAI. The third and forth samples were taken one week and one month after RAI. - In G1 and G3: The first blood sample was taken just before RAI. The second and third samples were taken one week and one month after RAI. - Just one blood sample was taken from each individual in normal control group.

Actual sample size reached: **100**

More than 1 sample in each individual

Actual sample size in each individual: **4**

In G2: The first blood sample was taken one month before RAI. The second sample was taken 30 days after taking omega-3 and just before RAI. The third and forth samples were taken one week and one month after RAI. In G1 and G3: The first blood sample was taken just before RAI. The second and third samples were taken one week and one month after RAI. - Just one blood sample was taken from each individual in normal control group.

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Because immunological factors are varied based on age and gender, in this study patients were nonrandomized allocated into different subgroups as their distribution were age and sex matched. Patients with UTC were divided into two groups based on RAI dose (100 and 150 mCi) determined by nuclear medicine specialist. Then patients in each group were divided into three subgroups nonrandomly as their distribution were age and sex matched: - Patients who received RAI (G1) - Patients who received omega-3 before RAI (G2) - Patients who received omega-3 after RAI (G3) A group of age and sex-matched healthy individuals with normal routine tests were selected as normal control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand St.

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2020-02-02, 1398/11/13

Ethics committee reference number

IR.SUMS.REC.1398.1302

Health conditions studied

1

Description of health condition studied

cancer

ICD-10 code

ICD-10 code description

cancer

Primary outcomes

1

Description

Cytokine change

Timepoint
30 days before RAI, Just before RAI, 7 & 30 days after RAI
Method of measurement
Cytometric bead-based assay

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who received omega-3 for 30 days before RAI therapy. - Based on radioiodine dosage, these patients were allocated in two groups with 100 mCi and 150 mCi. - These patients were instructed to take a soft-gel capsule of fish oil-derived omega-3 fatty acids (Best Formulations Inc., Los Angeles, CA, USA) containing 180 mg eicosapentaenoic acid and 120 mg docosahexaenoic acid daily for 30 consecutive days before RAI ablation.
Category
Treatment - Drugs

2

Description
Intervention group: Patients who received omega-3 for 30 days after RAI therapy. - Based on radioiodine dosage, These patients were allocated in two groups with 100 mCi and 150 mCi. - These Patients were instructed to take a soft-gel capsule of fish oil-derived omega-3 fatty acids (Best Formulations Inc., Los Angeles, CA, USA) containing 180 mg eicosapentaenoic acid and 120 mg docosahexaenoic acid daily for 30 consecutive days after RAI ablation.
Category
Treatment - Drugs

3

Description
Control group: Patients who received RAI therapy only. - Based on radioiodine dosage, these patients were allocated into two groups with 100 mCi and 150 mCi.
Category
Treatment - Other

4

Description
Normal controls group: Sex and age-matched individuals with no previous history of cancers and autoimmune diseases with no history of involvement with infectious disease in last month before sample collection and the results of their routine test were normal.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Nuclear Medicine Department at Namazi Hospital affiliated with Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mehrosadat Alavi
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Web page address
http://nimad.ac.ir
Grant name
Educated researcher grant (call 3)
Grant code / Reference number
958687
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Institute for Medical Research Development
Proportion provided by this source
99
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

2

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
National Institute for Research Development
Proportion provided by this source
1
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
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
Serum levels of 13 cytokines in each patient in different subgroups
When the data will become available and for how long
For ever
To whom data/document is available
Will be published as accessory file attached to the article
Under which criteria data/document could be used
Who has access to the full text of the article or ask the corresponding author via email
From where data/document is obtainable
Who refers to the full text of the article or through contact with the corresponding author
What processes are involved for a request to access data/document
Send an email to the corresponding author
Comments