

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

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Name of organization / entity

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

National Institute for Medical Research Development

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Web page address

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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
Full name of responsible person
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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

Contact

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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