

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Assessment of Zataria Multiflora essential oil on protection of salivary glands from radiation damage in differentiated thyroid cancer patients in a randomized double-blinded, placebo controlled, clinical trial

Protocol summary

Study aim

Determination of Zataria Multiflora essential oil effect on protection of salivary glands from radiation damage in thyroid cancer patients referred to nuclear medicine ward of Namazi hospital for radioactive iodine therapy in a randomized double-blinded, placebo controlled, clinical trial

Design

Double blinded randomized placebo controlled clinical trial, with parallel groups, phase 3, designed of 88 patients, randomized with rand function of the Excel software

Settings and conduct

Subjects will be randomly divided into 2 groups: A and B, using block randomization method. One is the intervention group and the other is the control group. The intervention and control groups will receive 20 drops of 2% essential oil of Zataria multiflora or placebo three times a day respectively from 1 week before the radioactive iodine therapy to 4 weeks after that. Salivary gland scans will be performed before receiving radioiodine and 6 months after that. The duration of the intervention will be 5 weeks. Before starting the study, patients will be divided into two groups of 44 people based on a checklist by block randomization method. Drug and placebo are labeled as A and B. Patients of group A will receive drug A and patients in group B will receive drug B. Study at the patient level, outcome evaluator and statistical analyzer of the results will be blinded.

Participants/Inclusion and exclusion criteria

Patients affected with thyroid cancer who are candidates for radio-iodine therapy

Intervention groups

Patients will be allocated in two groups and will receive Zataria Multiflora essential oil or placebo from one week before radioiodine therapy till four weeks after that.

Main outcome variables

Prevention of salivary glands' radiation damage

General information

Reason for update

Due to the covid 19 pandemia and the significant reduction of patients in the department and the failure of nuclear medicine devices, the date of patient recruitment and the sample size is changed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20140514017684N8**

Registration date: **2020-11-12, 1399/08/22**

Registration timing: **prospective**

Last update: **2022-09-08, 1401/06/17**

Update count: **1**

Registration date

2020-11-12, 1399/08/22

Registrant information

Name

Mahdi Haghghatafshar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4835

Email address

afsharm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-15, 1399/08/25

Expected recruitment end date

2021-09-16, 1400/06/25

Actual recruitment start date

2020-12-01, 1399/09/11

Actual recruitment end date

2021-09-16, 1400/06/25

Trial completion date

2022-03-16, 1400/12/25

Scientific title

Assessment of Zataria Multiflora essential oil on protection of salivary glands from radiation damage in differentiated thyroid cancer patients in a randomized double-blinded, placebo controlled, clinical trial

Public title

The effect of Zataria Multiflora on protection of salivary glands from radiation damage

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients affected with thyroid cancer who are candidates for radio-iodine therapy

Exclusion criteria:

Patients whose ages are less than 18 Patients who are affected with diseases affecting salivary glands such as Sjogren

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **88**

Actual sample size reached: **24**

More than 1 sample in each individual

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

2 parotid salivary glands and 2 submandibular salivary glands

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation, blocking, using the "rand" function of excel program, allocated as A and B

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug and placebo will be labeled as A and B by the drug producer. Patients allocated in group A and B will receive drug A and B respectively. Patients and chief researcher would not be aware of the coding.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Science, Karimkhan-e Zand Blvd

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2020-06-15, 1399/03/26

Ethics committee reference number

IR.SUMS.MED.REC.1399.244

Health conditions studied**1****Description of health condition studied**

Salivary glands' damage

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Ejection fraction of Parotid glands

Timepoint

Before radioactive iodine therapy and 6 months after that

Method of measurement

Salivary gland scintigraphy

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients will receive 20 drops of 2% solution of Zataria multiflora essential oil, commercially available as Gastrolith made by Barij Essential company from 1 week before receiving radioactive iodine to 4 weeks after that.

Category

Prevention

2

Description

Control group: Patients will receive 20 drops of placebo solution containing the basic solution of Gastrolith, three times a day from 1 week before receiving radioiodine to 4 weeks after that.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Namazi hospital

Full name of responsible person

Mahdi Haghghatafshar

Street address

Nuclear Medicine department, Namazi Hospital,
Namazi Square

City

Shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3647 4332

Email

nemazee_inf@sums.ac.ir

Web page address

<https://namazi.sums.ac.ir/page-Namazi/fa/65/form/pld5524>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaianzadeh

Street address

Central building of Shiraz University of Medical
Science, Karimkhan-e Zand Blvd

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

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

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahdi Haghghatafshar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Nuclear Medicine

Street address

Nuclear Medicine department, Namazi Hospital,
Namazi Square

City

Shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3647 4333

Email

afsharm@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahdi Haghghatafshar

Position

Associate professor

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7193613311
Phone
+98 71 3647 4333
Email
afsharm@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahdi Haghigatafshar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Nuclear Medicine
Street address
Nuclear Medicine department, Namazi Hospital,
Namazi Square
City
Shiraz
Province
Fars
Postal code
7193613311
Phone
+98 71 3647 4333
Email
afsharm@sums.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about the main outcome will be shared.

When the data will become available and for how long

After the article is published, it will be possible to access the data for one year.

To whom data/document is available

Researchers working in academic and scientific institutions are allowed to use data.

Under which criteria data/document could be used

Research use of the data will be allowed.

From where data/document is obtainable

Applicants for the data can send their request to the following e-mail. afsharm@sums.ac.ir

What processes are involved for a request to access data/document

Applicants must send their application to the e-mail address of the project manager. The requested data and documents will be sent to them within a maximum of one month.

Comments