Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Multiflura 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 Haghighatafshar

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 Haghighatafshar
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/pId5524

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
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Shiraz
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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 Haghighatafshar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Nuclear Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person
Mahdi Haghighatafshar

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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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
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