

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Studying the effect of using oral pilocarpine on absorbed salivary gland dose and side effects in patients on radioiodine therapy

#### Protocol summary

##### Summary

(1) Radioactive Iodine is used as one of the effective treatments in thyroid cancer therapy and could damage other organs such as salivary glands in addition to its uptake in the target tissue. In order to decrease the dysfunction of salivary glands in patients treated with radioiodine many different methods have been applied and one of the most effective approaches in prevention and treatment of these complications is administration of salivary stimulant agents such as Pilocarpine. (2) The purpose of this study is evaluating the effect of Pilocarpine on the absorbed dose and the side effect of salivary glands from radioiodine (3) in 20 patients at the initial phase among whom that are administering radioiodine in nuclear medicine department of Namazi hospital. Patients must have no salivary gland disease, no history of uncontrolled asthma, no bronchospasm, no heart failure, no acute iritis and no close angle glaucoma. They will be randomized in two intervention and control groups. (4,5) Patients from intervention or control group will receive respectively Pilocarpine or Placebo every 8 hours, start at 2 hours after administration of radioiodine. All groups will have scintigraphy at 2, 5, 13, 24 and 48 hours after administering I-131. Subjective symptoms such as mouth dryness, sialadenitis and pain in salivary glands will be checked up to 3 months. (6) At last the effect of administering Pilocarpine on radioiodine absorbed dose and the levels of radioiodine therapy side effects will be evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060917684N3**

Registration date: **2014-11-10, 1393/08/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-10, 1393/08/19

##### 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

Shiraz university of medical science, Vice chancellor for research

##### Expected recruitment start date

2014-11-01, 1393/08/10

##### Expected recruitment end date

2015-06-20, 1394/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Studying the effect of using oral pilocarpine on absorbed salivary gland dose and side effects in patients on radioiodine therapy

##### Public title

The effect of Pilocarpine on absorbed salivary gland dose in patients on radioiodine therapy.

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Patients with diagnosis of hyperthyroidism or thyroid cancer who are candidate for radioiodine therapy  
Exclusion criteria: patient with history of uncontrolled asthma; bronchospasm; severe COPD; heart failure; acute iritis; close angle glaucoma; patient use antihypertensive drugs; history of salivary gland disease; no patient consent.

## Age

From **20 years** old to **65 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz university of medical science, Ethics Committee

##### Street address

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

##### City

Shiraz

##### Postal code

14336 - 71348

#### Approval date

2014-05-20, 1393/02/30

#### Ethics committee reference number

CT-P-9366-6246

## Health conditions studied

### 1

#### Description of health condition studied

Thyroid Cancer therapy with I-131

#### ICD-10 code

C73-C75

#### ICD-10 code description

Malignant neoplasms of thyroid and other endocrine glands

## Primary outcomes

### 1

#### Description

Organ dose per administered I131 Activity (ODPA)

#### Timepoint

1,2,3,4,5,13,25,48 h after receiving radio-iodine 131

#### Method of measurement

By scintigraphy and MIRD Schema software calculations

## Secondary outcomes

### 1

#### Description

Side effects of radio-iodine 131

#### Timepoint

Every 4-6 weeks

#### Method of measurement

Asking the patient

## Intervention groups

### 1

#### Description

Intervention group:Using oral Pilocarpine every 8 hours, start at 2 hours after administration of radioiodine.

#### Category

Prevention

### 2

#### Description

Control group:Using oral Placebo every 8 hours, start at 2 hours after administration of radioiodine.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shiraz Namazi Hospital

##### Full name of responsible person

Nuclear medicine and molecular imaging research center

##### Street address

nuclear medicine department, Namazi hospital, Namazi Square

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz university of medical science, Vice chancellor for research

**Full name of responsible person**

Zahra Pandkhahi

**Street address**

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

**City**

Shiraz

**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 science, Vice chancellor for research

**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*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Shiraz university of medical science

**Full name of responsible person**

Nuclear medicine and molecular imaging research center

**Position**

Expert of the center

**Other areas of specialty/work****Street address**

Nuclear Medicine department, Namazi Hospital, Namazi Square

**City**

Shiraz

**Postal code**

11351-71937

**Phone**

+98 71 1612 5330

**Fax****Email**

nmmirc@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shiraz university of medical science

**Full name of responsible person**

Nuclear medicine and molecular imaging research center

**Position**

Nuclear medicine Specialist

**Other areas of specialty/work****Street address**

Nuclear Medicine department, Namazi Hospital, Namazi Square

**City**

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**Fax****Email**

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## Person responsible for updating data

**Contact**

## 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*