

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

Shiraz

Postal code

11351-71937

Phone

+98 71 1612 5330

Fax**Email**

nmmirc@yahoo.com

Web page address

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