

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The study of the effect of chewing sugar-free gums after receiving I-131, on I-131 absorbed dose and its side effects in the salivary glands of patients with differentiated thyroid cancer

Protocol summary

Summary

(1) I-131 administration is one of the known treatments which is used after thyroidectomy in differentiated thyroid cancer patients. In spite of the fact that this is effective in destroying tumor tissue remnant, it has many side effects. One of them is transient or permanent damage and inflammation of salivary glands. (2) This study evaluates the effect of chewing sugar-free gums, after administering radioactive iodine, absorbed dose and incidence of side effects in salivary glands of thyroid cancer patients. (3,4) 60 patients will be chosen randomly among the patients who are administered radioactive iodine in nuclear medicine department at Shiraz Namazi hospital. They shouldn't have any positive history of previous salivary gland diseases, phenylketonuria, collagen tissue diseases and head and neck radiotherapy. They will be divided into two intervention and one control groups. (5) The two intervention groups will start chewing sugar-free gums, one from the first day after hospitalization and the other from the second day. All groups will have scintigraphy at 2, 5, 13, 24 and 48 hours after administering I-131. Also incidence rate of Sialadenitis and Xerostomia will be evaluated monthly from a week after hospitalization up to 6 months. (6) Finally we will evaluate the effect of chewing sugar-free gums after receiving radioactive iodine, on its absorbed dose and side effects in salivary glands of patients with differentiated thyroid cancer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062117684N5**
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 Haghighatafshar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3647 4835

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz university of medical science, Vice chancellor for research

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-06-19, 1394/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of chewing sugar-free gums after receiving I-131, on I-131 absorbed dose and its side effects in the salivary glands of patients with differentiated thyroid cancer

Public title

Evaluating the effect of chewing sugar-free gums after receiving I-131, on absorbed dose in the salivary glands.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Patients older than 20 years for whom thyroidectomy has been performed for 4-6 weeks prior to initiation of the study due to differentiated thyroid cancer and are referred to Namazi Hospital Center of Nuclear Medicine for ablative radioactive iodine -131 therapy; 2- Patients who have received low-iodine diet for two weeks; 3- Patients must be at hypothyroid state at the time of the study; 4- Patients should have signed the informed consent form and should give permission for their participation in the study; Exclusion Criteria: 1- Any positive history of previous salivary gland diseases; 2- Any positive history of collagen tissue diseases; 3- Positive history of Phenylketonuria; 4- Positive history of using diuretics, Antihistamines, Antidepressants or Anticholinergic medications; 5- Positive history of previously receiving Radiotherapy at Head & Neck region; 6- Positive history of previous treatment with radioiodine (I-131); 7- Difficulty in taking large amount of fluid;

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not 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-9368-6618

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**

Radioiodine absorbed dose

Timepoint

5 time points : At 2, 5, 13, 24 & 48 hours after receiving Radioiodine

Method of measurement

Radioiodine absorbed dose will be measured by scintigraphy and the amounts measured will be interpreted by MIRD Schema software.

Secondary outcomes**1****Description**

Incidence rate of Sialadenitis and Xerostomia in under study patients

Timepoint

At time points: 1 week after initial admission period then monthly follow ups till 6 months

Method of measurement

By making phone calls at chosen time points and collecting subjective data about patients' symptoms

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

Intervention group(1): using sugar-free chewing gum from the first day of treatment.

Category

Prevention

2

Description

Intervention group(2): using sugar-free chewing gum from the second day of treatment

Category

Prevention

3

Description

Control Group: Do not use chewing gum

Category

N/A

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

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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