

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Treatment efficacy of high versus low dose post thyroidectomy iodine ablation in intermediate risk patients with differentiated thyroid cancer , referring to thyroid clinic of nuclear medicine department of GHAEH hospital in the years 1392 to 1395.

Protocol summary

Summary

For radioiodine ablation in differentiated thyroid cancer patients, low dose of Iodine 131(30 milli-curies) is recommended for low risk patients and for high risk ones, high dose iodine 131(100 milli-curies or more) is recommended; however, there is no prompt recommendation for optimal dose of radioiodine ablation in intermediate risk patients. This study is aimed to compare the treatment efficacy of low versus high dose radioiodine therapy in intermediate risk thyroid cancer patients. This study will be carried out on 110 adult patients who place in intermediate risk category of differentiated thyroid carcinoma . They will be divided in two groups each containing 55 patients and will receive 30 or 150 milli-curies of I131 orally in one session, being randomized. After radioiodine therapy, They will be followed for 1 year. The treatment response will be evaluated based on the laboratory data, ultrasonography and the diagnostic whole body iodine scan (if performed), after 1 year according to the new response assessment criteria based on the last published version of American Thyroid Association guidelines. The therapeutic response will be either excellent response, acceptable response or incomplete response. So, the therapeutic response of high(150 milli-curies) and low dose(30 milli-curies) radioiodine ablation in intermediate risk differentiated thyroid cancer patients will be evaluated and compared. Also, the possible relationship between age, sex, the first serum thyroglobulin and anti thyroglobulin levels with the therapeutic response will be illustrated, too.

General information

Acronym

LOH(low or high)

IRCT registration information

IRCT registration number: **IRCT2016011626038N1**

Registration date: **2016-05-08, 1395/02/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-08, 1395/02/19

Registrant information

Name

Athena Aghaee

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Nuclear Medicine Research Center; Mashhad University of Medical Sciences

Expected recruitment start date

2014-12-31, 1393/10/10

Expected recruitment end date

2016-10-31, 1395/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment efficacy of high versus low dose post thyroidectomy iodine ablation in intermediate risk patients with differentiated thyroid cancer , referring to thyroid clinic of nuclear medicine department of GHAEM hospital in the years 1392 to 1395.

Public title

comparing treatment efficacy of high versus low dose iodine ablation in intermediate risk thyroid cancer patients referring to thyroid clinic of nuclear medicine department of GHAEM hospital in the years 1392 to 1395

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion:age more than 18 years/ diagnosis of DTC by a reliable pathology/history of total thyroidectomy / recieved no other treatments such as radiotherapy and/or iodine ablation after surgery/ no evidence of distant metastasis at initial evaluation/ categorizing in either of these groups: age more than 45 yeras: T1N1b,T2N0,T2N1a,T3N0; age less than 45 years: T21a,T2N1b,T3N0,T3N1a Exclusion: incomplete thyroid surgery; first serum Throglobulin level more than 60 ng/dl; distant metastasis/ T4

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Park square,
Mashhad

City

mashhad

Postal code

Approval date

2013-10-05, 1392/07/13

Ethics committee reference number

IR.MUMS.REC.1392.150

Health conditions studied

1

Description of health condition studied

Malignant neoplasm of thyroid gland

ICD-10 code

(C73)

ICD-10 code description

Malignant neoplasm of thyroid gland

Primary outcomes

1

Description

response to treatment categorize as 3 groups: excellent response, acceptable response and incomplete response

Timepoint

1 year after treatment

Method of measurement

according to patients lab test in the off drug status, such as thyroglobulin, anti thyroglobulin , neck ultrasonography and diagostic whole body iodine scan,if needed

Secondary outcomes

1

Description

serum thyroglobulin

Timepoint

1 year after treatment

Method of measurement

lab data

Intervention groups

1

Description

administration of 150 mci of I131

Category

Treatment - Drugs

2

Description

administration of 30mci of I131.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital-Nuclear Medicine Department

Full name of responsible person

Dr.Athena Aghaee

Street address

Ghaem Hospital; Ahmad Abad Avenue

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nuclear Medicine Research Center

Full name of responsible person

Dr.Seyed Rasool Zakavi

Street address

Ghaem Hospital

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Nuclear Medicine Research Center

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**

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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