

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison between different fixed and calculated doses of I-131 in treatment of patients with Graves' disease

Protocol summary

Summary

Radioiodine therapy is an effective treatment in hyperthyroidism. However there is no consensus on the optimal dose regimen of I-131 administration. We aim to compare the efficacy of different fixed versus different calculated doses of I-131 in treatment of patients with Graves' disease. This is a clinical randomized trial on 300 Graves' patients whom are referred for radioiodine therapy to nuclear medicine department of Ghaem hospital. After signing the written consent, the patients will be randomly treated with different fixed and calculated doses of 131 iodine and the treatment response as well as complications of treatment will be compared between different groups at 1, 3, 6 and 12 months post iodine therapy.

General information

Acronym

MASRIG

IRCT registration information

IRCT registration number: **IRCT2016020217006N1**

Registration date: **2017-09-10, 1396/06/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-10, 1396/06/19

Registrant information

Name

Narjess Khatoun Ayati

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1801 2782

Email address

ayatin@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2019-03-02, 1397/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between different fixed and calculated doses of I-131 in treatment of patients with Graves' disease

Public title

Radioiodine therapy in Graves' disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 18; Confirmed cases of Graves' disease; No previous history of radioiodine therapy; No previous history of thyroid surgery Exclusion criteria: pregnancy; lactation; severe ophtalmopathy; no desire to join to study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

F2. Ghoreishi Building. Daneshgah Street. Mashhad

City

Mashhad

Postal code

Approval date

2014-01-29, 1392/11/09

Ethics committee reference number

920800

Health conditions studied

1

Description of health condition studied

Graves

ICD-10 code

E05.0

ICD-10 code description

Thyrotoxicosis with diffuse goiter

Primary outcomes

1

Description

TSH, T3, T4

Timepoint

1,3,6,12 months post radioiodine therapy

Method of measurement

Blood test

2

Description

Thyroid volume

Timepoint

1,3,6,12 months post radioiodine therapy

Method of measurement

Ultrasonography

3

Description

Thyroid weight

Timepoint

1,3,6,12 months post radioiodine therapy

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fixed Low Dose (7 mCi)I-131/Single dose

Category

Treatment - Drugs

2

Description

Intervention group: Fixed High Dose (15 mCi) I-131/Single dose

Category

Treatment - Drugs

3

Description

Intervention group: Calculated Dose (100 micro Currie I-131/gr Thyroid tissue) / Single dose

Category

Treatment - Drugs

4

Description

Intervention group: Calculated Dose (150 micro Currie I-131/gr Thyroid tissue) / Single dose

Category

Treatment - Drugs

5

Description

Intervention group: Calculated Dose (200 micro Currie I-131/gr Thyroid tissue) / Single dose

Category

Treatment - Drugs

6

Description

Intervention group: Calculated Dose (300 micro Currie I-131/gr Thyroid tissue) / Single dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Nuclear Medicine Research Center

Full name of responsible person

Dr. Narjes Ayati

Street address

Ahmadabad Street, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Dr. Mohsen. Tafaghodi

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F2. Ghoreishi Building. Daneshgah Street. Mashhad

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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

Mashhad University of Medical Sciences, 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

Ghaem Nuclear Medicine Reserch Center

Full name of responsible person

Dr. Narjess Ayati

Position

Assiastant Professor of Nuclear Mrdicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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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