Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

A randomized clinical trial for the evaluation of the efficacy of 30 mCi versus 100 mCi, 131I for ablation of residual thyroid tissue

Protocol summary

Summary

Ablation of the thyroid residue with I-131 after thyroidectomy is performed in the management of patients with differentiated thyroid cancers but there is no confidence over using lower or higher doses. We aimed this study to determine whether low doses of I-131 (30 mCi) could provide acceptable therapeutic results as comparing with optimal 100 mCi I-131 for ablating of thyroid residue after total/near total thyroidectomy. More patient's radiation and biological damages are noticed in higher doses and conversely ineffective treatment may be considered in lower doses of radioiodine therapy. 341 patients with low risk differentiated thyroid carcinoma (without evidence of capsular/vascular/lymphatic invasion or distant metastases) were randomly allocated into group A (30mCi) and B (100mCi). Thyroglobuline (Tg), Thyroid stimulating hormone (TSH) and anti-Tg were measured and also thyroid bed sonography, whole body scan (WBS) and plannimetry of the scans were carried out for all patients before and 6 months after I-131 therapy. Patients' response to the therapy was evaluated based on post-treatment WBS and Tg values. Absent uptake in thyroid bed and Tg value less than 4ng/ml were considered as complete response. The rate of treatment response in group A and B were compared with Chi square test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706171100N2**
Registration date: **2011-08-16, 1390/05/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-08-16, 1390/05/25

Registrant information

Name

Davood Beiki

Name of organization / entity

Research Institute for Nuclear Medicine, Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2005-06-18, 1384/03/28

Expected recruitment end date

2008-10-19, 1387/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial for the evaluation of the efficacy of 30 mCi versus 100 mCi, 131I for ablation of residual thyroid tissue

Public title

Comparison between low and high doses of radioactive iodine in the treatment of thyroid cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with differentiated thyroid carcinoma (DTC): without any history of ablation therapy; with no palpable mass in the neck; with no evidence of capsular; vascular or lymph node invasion. Exclusion criteria: Any area of I-131 uptake in post-treatment whole body scan; Failing to follow the patients.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **341**

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

Tehran University of Medical Sciences

Street address

Keshavarz boulevard, Ghods str.

City

Tehran

Postal code

Approval date

2004-06-14, 1383/03/25

Ethics committee reference number

132.2131

Health conditions studied

1

Description of health condition studied

Diffrentiated Thyroid Cancer

ICD-10 code

C73

ICD-10 code description

Malignant neoplasm of thyroid gland

Primary outcomes

1

Description

Response to treatment with I-131

Timepoint

6 Months

Method of measurement

Tg, AntiTg tests and whole body scan with I-131

Secondary outcomes

1

Description

disease recurrence

Timepoint

6 and 12 months

Method of measurement

Lab measurements, sonography and clinical assessment

Intervention groups

1

Description

Low dose (30 mCi)

Category

Treatment - Drugs

2

Description

High dose (100 mCi) of I-131

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute for Nuclear Medicine, Tehran University of Medical Sciences

Full name of responsible person

Dr Babak Fallahi

Street address

Research Institute for Nuclear Medicine, Shariati Hospital, N Kargar Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of

Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

Street address

Keshavarz boulevard

City

Tehran

Grant name

-

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

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