

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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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Person responsible for updating data

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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