

# Multicentre randomised trial of High dose versus Low dose radioiodine, with or without recombinant human thyroid stimulating hormone, for remnant ablation following surgery for differentiated thyroid cancer

<b>Submission date</b> 14/06/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-radioactive-iodine-treatment-for-thyroid-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2005-003687-37

**IRAS number****ClinicalTrials.gov number**

NCT00415233

**Secondary identifying numbers**

BRD/05/83

## **Study information**

**Scientific Title**

Multicentre randomised trial of High dose versus Low dose radioiodine, with or without recombinant human thyroid stimulating hormone, for remnant ablation following surgery for differentiated thyroid cancer

**Acronym**

HiLo

**Study objectives**

1. To examine whether a low administrative dose (1.1 GBq) of radioiodine has a similar remnant ablation success rate as a high dose (3.7 GBq)
2. To examine whether patients given recombinant human Thyroid Stimulating Hormone (rhTSH) have a similar ablation success rate to those who discontinue thyroid hormone replacement

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Cambridgeshire 4 Research Ethics Committee, 14/07/2006, ref: 06/MRE05/39

**Study design**

Factorial randomised trial (a trial of equivalence)

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

## Differentiated thyroid cancer

### Interventions

Following surgery, eligible patients will be approached for consent. Those who agree will be randomised to one of the following groups:

Group A: rhTSH followed by 1.1 GBq of radioiodine ablation

Group B: rhTSH followed by 3.7 GBq of radioiodine ablation

Group C: Hormone withdrawal (i.e., no rhTSH) followed by 1.1 GBq of radioiodine ablation

Group D: Hormone withdrawal (i.e., no rhTSH) followed by 3.7 GBq of radioiodine ablation

### Intervention Type

Mixed

### Primary outcome measure

The percentage of patients who have a successful remnant ablation six to eight months after radioiodine administration

### Secondary outcome measures

1. Quality of life during treatment period
2. Loco-regional recurrence
3. Distant metastases

Long term outcomes:

1. Survival and incidence of secondary primary malignancies

### Overall study start date

01/09/2006

### Completion date

01/09/2010

## Eligibility

### Key inclusion criteria

1. Histological confirmation of differentiated thyroid carcinoma
2. Patients with tumour stage pT1-T3; NX, N0 or N1; M0 (TNM Classification of Malignant Tumours 6th edition 2002)
3. Patients who have undergone total thyroidectomy with or without lymph node dissection
4. Patients who require radioiodine ablation
5. Aged 16 to 80 years
6. World Health Organization (WHO) performance status zero to two (self caring)
7. All known tumour resected (R0)

### Participant type(s)

Patient

### Age group

Adult

### Sex

Both

### **Target number of participants**

468

### **Key exclusion criteria**

1. Hurthle cell carcinoma and aggressive variants including tall cell, insular, poorly differentiated, diffuse sclerosing and widely invasive subtypes; anaplastic and medullary carcinoma
2. Patients who have a contrast Computed Tomography (CT) scan up to three months before ablation
3. Patients for whom rhTSH requirement is mandatory
4. Patients who have severe co-morbid conditions (e.g., unstable angina, recent heart attack or stroke, severe labile hypertension, dementia, on dialysis, with tracheostomy needing care, learning difficulties and anybody who may not be able to comply with radiation protection issues or need frequent nursing/medical supervision which puts staff at risk of unacceptable radiation exposure)
5. Other cancers excluding basal cell carcinoma of the skin or in situ carcinoma of the cervix
6. Pregnant women or women who are breastfeeding
7. Patients with stage pT4 or M1 (if detected clinically or by other investigations)
8. Previous <sup>131</sup>I or <sup>123</sup>I pre-ablation scan
9. Previous treatment for thyroid cancer (except surgery)

### **Date of first enrolment**

01/01/2007

### **Date of final enrolment**

31/07/2010

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

Cancer Research UK & UCL Cancer Trials Centre

London

United Kingdom

W1T 4TJ

## **Sponsor information**

### **Organisation**

University College London (UK)

### Sponsor details

Medical School Administration  
Gower Street  
London  
England  
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### Sponsor type

University/education

### ROR

<https://ror.org/02jx3x895>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Results article</a>	results	03/05/2012		Yes	No