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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

Submission date 14/06/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 11/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 19/10/2018	**Condition category** Cancer	[_] 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

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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 131I or 123I 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
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Sponsor information

Organisation
University College London (UK)

Sponsor details
Medical School Administration
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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?
Plain English results				No	Yes
Results article	results	03/05/2012		Yes	No