

HiLo

A multicentre randomised trial of high versus low dose radioiodine, with or without rhTSH, for remnant ablation following surgery for thyroid cancer

Chief Investigator	Dr Ujjal Mallick and Dr Clive Harmer
Design	Randomised phase III trial
Aims	<ul style="list-style-type: none">• To determine whether 1.1 GBq of radioiodine has a similar remnant ablation success rate as 3.7 GBq• To determine whether patients given rhTSH before ablation have a similar ablation success rate to those who discontinue thyroid hormone replacement
Patients	468 patients with differentiated thyroid cancer
Eligibility	<ul style="list-style-type: none">• Histological confirmation of differentiated thyroid carcinoma• Tumour stage pT1-T3; NX, N0 or N1, M0 (TNM 6th edition)• Have had total thyroidectomy• Age 16-80 years• WHO performance status 0 - 2 (self caring)• All known tumour resected (R0)
Main outcome	Success of ablation 6-8 months after radioiodine treatment (neck & whole body diagnostic scan and serum thyroglobulin)
Secondary outcomes	<ul style="list-style-type: none">• Quality of life• Cost-effectiveness (eg length of hospital stay)• Recurrence and survival• Incidence of second primary tumours
Other assessments	<ul style="list-style-type: none">• Pre-ablation scan using Technetium 99m (avoids stunning)• SF36 quality of life questionnaire• Patient survey on daily living and work
Treatment arms	117 patients in each arm (factorial design): A. rhTSH & continue thyroid hormone replacement followed by 1.1 GBq radioiodine ablation B. rhTSH & continue thyroid hormone replacement followed by 3.7 GBq radioiodine ablation C. thyroid hormone replacement discontinued (or not started at all) followed by 1.1 GBq radioiodine ablation D. thyroid hormone replacement discontinued (or not started at all) followed by 3.7 GBq radioiodine ablation
Funding body	Cancer Research UK
Open to	Centres in the UK NCRN, and possibly overseas
Trial duration	3 to 4 years
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Other members of the trial team	Patrick Bradley, Penelope Clark, Sue Clarke, Jayne Franklyn, Allan Hackshaw, Masud Haq, Rhys John, Ralph McCready, Kathryn Monson, Laura Moss, Alice Nicol, Chris Nutting, James Smellie