

# HiLo

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

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