### 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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<tr>
<th><strong>Chief Investigator</strong></th>
<th>Dr Ujjal Mallick and Dr Clive Harmer</th>
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<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Randomised phase III trial</td>
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| **Aims**               | • 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**        | • 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** | • Quality of life  
                          • Cost-effectiveness (eg length of hospital stay)  
                          • Recurrence and survival  
                          • Incidence of second primary tumours |
| **Other assessments**  | • 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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