HiLo

HiLo - 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.

TRIAL SUMMARY

BACKGROUND

Thyroid cancer is the most frequently occurring malignant endocrine tumour. Differentiated thyroid cancer (DTC) is the most common subtype and is usually curable with a 10-year survival of about 90%. Most patients with DTC undergo total or near-total thyroidectomy followed by radioiodine to ablate residual normal thyroid tissue (also reduce local recurrence, distant recurrence and death from thyroid cancer). Radioiodine ablation is standard practice in all centres included in this trial. There is controversy over the lowest effective activity of radioiodine for ablation. Most clinicians use 3-3.7 GBq, while others use 1.1 GBq. There are several important advantages to both the patient and the NHS of using a lower activity: reduced risk of second primary malignancies, shorter hospital stay, reduced exposure to environment.

A systematic review of all published randomised trials using high and low activity radioiodine for ablation has been undertaken (co-ordinated by Allan Hackshaw, Cancer Research UK & UCL Cancer Trials Centre). No useful conclusions can be drawn from these trials since the results are consistent with there being either no difference between the activities used or that a high activity is more effective.

After thyroidectomy, patients require thyroid hormone replacement, but this is stopped several weeks before radioiodine ablation. During this period they suffer from symptoms of hypothyroidism. Recombinant human thyroid stimulating hormone (rhTSH) can be given before ablation and has the advantage of allowing patients to continue with thyroid hormone. This significantly improves their quality of life during the treatment. There is, however, uncertainty over whether successful ablation rates differ between patients given rhTSH and those who discontinue thyroid hormone.

AIMS

1. To show that a low activity (1.1 GBq) of radioiodine has a similar remnant ablation success rate as a high activity (3.7 GBq).
2. To show that patients given rhTSH have a similar ablation success rate to those who discontinue thyroid hormone replacement

METHODS

Patients with differentiated thyroid cancer who have undergone total thyroidectomy will be recruited to this multi-centre trial (coordinated at the Cancer Research UK & UCL Cancer Trial Centre). Patients will be randomly assigned to one of following four groups:

A. rhTSH & continue thyroid hormone replacement followed by 1.1 GBq radioiodine ablation (N=117)
B. rhTSH & continue thyroid hormone replacement followed by 3.7 GBq radioiodine ablation (N=117)
C. thyroid hormone replacement discontinued (or not started at all) followed by 1.1 GBq radioiodine ablation (N=117)
D. thyroid hormone replacement discontinued (or not started at all) followed by 3.7 GBq radioiodine ablation (N=117)

Patients will have a pre-ablation ^{99m}Tc pertechnetate scan to assess the size of the remnant.
Patients will be assessed 9 months after ablation to determine the success of ablation using ^{131}I scans (whole body images, thyroid image, thyroid uptake) and thyroglobulin measurements.

FOR FURTHER INFORMATION CONTACT:

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