

## PRESS RELEASE

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### Patients with low risk thyroid cancer can receive lower doses of radiation treatment: new results from the HiLo trial

**Glasgow, UK:** Thyroid cancer patients whose disease is at low risk of returning can be treated safely with a smaller amount of radiation following surgery, according to results from the world's longest running trial to investigate this.

Dr Jonathan Wadsley, a consultant clinical oncologist at the Weston Park Hospital, Sheffield, UK, and chair of the National Cancer Research Institute (NCRI) Thyroid Cancer Subgroup, told the 2018 NCRI Cancer Conference today (Monday) that the latest results from the HiLo trial showed there was no significant difference in the recurrence rate between patients given a low radiation dose compared to the standard, higher dose. He said this meant that international guidelines could be updated to recommend the lower dose in low risk patients and these patients would benefit from fewer side effects and long-term complications, and a more convenient treatment.

He reported results from 434 patients with low risk thyroid cancer in the HiLo trial with a median (average) follow-up time of 6.5 years. The patients were randomised to receive low administered radioactive iodine activity (RAI) of 1.1GBq, or the standard high RAI of 3.7GBq [1]. They also received either Thyrogen (a genetically-engineered thyroid stimulating hormone, TSH), which stimulates thyroid cancer cells to absorb as much radioactive iodine as possible, making it more effective, or they were asked to stop taking their thyroid hormone tablets, which achieves the same effect by allowing levels of their natural TSH to rise.

Dr Wadsley explained: "Activity is a measure of the amount of radiation that is administered to the patient in the form of a radioactive isotope of iodine. The aim of the treatment is to destroy any residual normal thyroid tissue and thyroid cancer cells following surgery to remove the thyroid gland. The treatment is most commonly given as a capsule to swallow. As a general principle, we would always wish to give the lowest quantity of radiation possible to prevent the recurrence of thyroid cancer. This is to reduce the risk of longer-term side effects from the treatment, most importantly reducing the risk of the treatment causing another cancer in the future. In our study the low activity 1.1GBq dose was less than a third of the higher activity 3.7GBq dose but has been proven to be as effective."

During the nearly seven years of follow-up, there were 21 recurrences of cancer (11 and 10 with 1.1GBq and 3.7GBq respectively). The recurrence rates were similar between the two doses, and also between patients using Thyrogen or thyroid hormone withdrawal.

"The study showed that patients receiving a lower activity experienced fewer side effects, in particular less risk of feeling sick or suffering damage to the salivary glands, which can potentially lead to a permanently dry mouth. The use of a lower activity also raises the possibility of giving the treatment in one day rather than having to admit patients to be nursed in isolation for two to three nights. This is required for the higher activity due to radiation protection

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regulations to avoid exposing the general public to unnecessary radiation, but can be particularly distressing for patients as they can only have very limited contact with other people during this time, which is particularly hard for someone with a recent cancer diagnosis. Therefore, not only is lower activity preferable for patients, it can also result in cost savings to the health service,” said Dr Wadsley.

“The study also showed that quality of life and ability to continue normal activities was much better for patients receiving Thyrogen than those using thyroid hormone withdrawal. If thyroid hormone withdrawal is used, patients have to come off their regular medication for at least two weeks. This leaves them feeling extremely tired and in some cases quite depressed.”

He said that the HiLo trial had the longest follow-up time of any other randomised study worldwide. Until now, there had not been enough evidence for international guidelines to do more than make weak recommendations about using 1.1GBq in low risk patients, due to the limited data and only short-term follow-up.

“Now that we have confirmation that there is no difference in recurrence rates over a longer follow-up period, these recommendations can be strengthened and clinicians and patients can be confident that use of the lower activity is acceptable and in fact preferable,” he concluded.

The HiLo trial has finished and now the researchers are investigating whether a group of patients can be identified that have such a low risk of recurrence of their thyroid cancer that they do not require radioiodine therapy at all. The IoN trial (Iodine or Not) is allocating patients with very low risk thyroid cancer to have radioiodine therapy or careful observation alone to determine whether there is any difference in recurrence rates and whether or not these patients could avoid iodine treatment altogether.

Dr Martin Forster from University College London, who is chair of the NCRI Head and Neck Clinical Studies Group and was not involved with this research said: “Nearly seven years of follow-up data from the HiLo trial provides us with confidence that the lower 1.1GBq radiation dose for patients with low risk thyroid cancer is a safe and effective treatment, and that international guidelines can be updated to reflect this. For many patients, the treatment and how it is delivered, as well as the short and long-term side effects, can have a big impact on their lives. The HiLo trial is a good example of a well-conducted clinical trial that can make a real difference to the quality of life for these patients. We look forward to the results of the IoN trial, which could determine whether some patients have such a low risk of their cancer returning that they could be spared radioiodine treatment completely.”

Thyroid cancer is rare, with approximately 3,500 cases in the UK each year, less than 1% of the total annual number of cancers. Low risk thyroid cancers have a good survival rate with approximately 99% patients surviving for ten years or more.

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## Notes to editors

**Abstract no: LBA 2148**, “Recurrence rates after low dose radioiodine ablation for differentiated thyroid cancer within the NCRI HiLo trial.” **Clinical Trials Showcase session, Room M1, 16.30 hrs, Monday 5 November.**

[1] GBq stands for gigabecquerel. One becquerel is the activity of a quantity of radioactive material in which one nucleus decays per second. 1GBq is 1,000,000,000 becquerels.

The study was funded by Cancer Research UK.

### About the NCRI Cancer Conference

The NCRI Cancer Conference is the UK’s largest forum showcasing the latest advances in cancer research. The Conference provides a platform for researchers, clinicians, people affected by cancer and industry representatives to come together to discuss, present and showcase high-quality research. Informative and interactive educational sessions attract over 1,500 delegates each year and create the ideal setting to establish new collaborations with key stakeholders in cancer research.

The NCRI Cancer Conference is taking place from 4-6 November 2018 at the Scottish Event Campus, Glasgow, UK.

For more information visit <https://conference.ncri.org.uk/>

### About the NCRI

The National Cancer Research Institute (NCRI) is a UK-wide partnership of cancer research funders, established in 2001. Its 19 member organisations work together to accelerate progress in cancer-related research through collaboration, to improve health and quality of life.

NCRI works to coordinate research related to cancer, to improve the quality and relevance of research and to accelerate translation of research into clinical practice for the benefit of patients.

NCRI Partners are: Biotechnology and Biological Sciences Research Council (BBSRC); Bloodwise; Brain Tumour Research; Breast Cancer Now; Cancer Research UK; Children with Cancer UK; Department of Health and Social Care; Economic and Social Research Council (ESRC); Macmillan Cancer Support; Marie Curie; Medical Research Council (MRC); Northern Ireland Health and Social Care Public Health Agency (Research & Development Department); Pancreatic Cancer Research Fund; Prostate Cancer UK; Roy Castle Lung Cancer Foundation; Scottish Government Health Directorates (Chief Scientist Office); Tenovus Cancer Care; The Wellcome Trust and Welsh Assembly Government (Health and Care Research Wales).

For more information visit [www.ncri.org.uk](http://www.ncri.org.uk)

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