

PRESS RELEASE FROM CANCER TRIALS IRELAND

Results of 15-year TAILORx cancer trial finds most women with early stage breast cancer can avoid chemotherapy

690 women from Ireland participated in this ground-breaking trial

FOR IMMEDIATE PUBLICATION: (Sunday, 3rd June 2018) Results of a ground-breaking breast cancer trial, in which 690 women from Ireland participated, show that chemotherapy can be avoided for 70 per cent of women with the most common type of early stage breast cancer (HR-positive, HER2-negative, node-negative breast cancer).

The findings suggest that chemotherapy may be considered for the remaining 30 per cent of women.

The trial, known as TAILORx, is one of the first large-scale trials to examine a methodology for personalising post-operative cancer treatment.

Using a 21-gene expression test the trial identified the 70 per cent women with a low risk of cancer recurrence after surgery who could avoid chemotherapy.

The trial involved 10,273 women with early-stage breast cancer across 1,182 research units in Ireland, United States, Australia, Canada, New Zealand and Peru.

The Irish arm of the trial was conducted by Cancer Trials Ireland and led by Professor Maccon Keane, Consultant Medical Oncologist, University Hospital Galway, as the Chief Investigator.

St Vincent's University Hospital in Dublin had the second highest number of participating patients from the 1,182 research units involved in the trial.

The results were announced today (*3rd June*) in Chicago at the Annual Meeting at the American Society of Clinical Oncology (ASCO) which brings together more than 32,000 oncology professionals from around the world to discuss state-of-the-art treatments and new therapies.

The Chief Investigator for Ireland, Professor Keane, said:

"The TAILORx trial result is a major advance in precision medicine for women with hormone receptor positive node negative breast cancer.

"It confirms that using the 21-gene expression test on tumours we can identify which women will benefit from endocrine (hormone) therapy only, thus eliminating the need for them to have chemotherapy.

"It also helps identify those women with this disease who really do benefit from the chemotherapy they receive.

"Having the trial in Ireland has enabled more personalised treatment recommendations for women with this stage and type of breast cancer as we have had access to the test through the HSE since 2011.

"Irish women contributed significantly to this trial and can be rightly proud of their input into improving care for future women who present with breast cancer.

Commenting on the results, Professor Bryan Hennessy, Clinical Lead, Cancer Trials Ireland, said:

“This is a globally important breast cancer trial. These results will inform clinical decision-making and in future many women with certain types of early-stage breast cancer can avoid chemotherapy, without impacting on the success of their treatment.

“We are delighted that with the support of these patients, our research teams, under the umbrella of Cancer Trials Ireland, were able to play a leading role in this research”, he said.

Commenting on the results, Eibhlin Mulroe, CEO, Cancer Trials Ireland, said:

“The fact that 690 women with breast cancer in Ireland have been involved in this global trial demonstrates the world-class capability of our unique network of cancer trials research units spread across Ireland and reflects the patients’ generosity to help future generations. We owe those who took part in this trial our thanks.

“Not only did the trial provide great relief for women in Ireland who participated and avoided three months of chemotherapy, it delivered considerable cost savings to the HSE, she said.

The trial was supported by the National Cancer Institute (NCI), part of the National Institutes of Health, and designed and led by the ECOG-ACRIN Cancer Research Group. Findings from the study will be published in *The New England Journal of Medicine*.

Patients involved in the study are still being followed up by their doctor and information continues to be collected thanks to the ongoing commitment of patients to the study.

TAILORx is a phase 3 clinical trial. The concept for the trial arose in 2003 and was designed to provide an evidence-based answer to the question of whether hormone therapy alone is not inferior to hormone therapy plus chemotherapy. The trial used a molecular test (Oncotype DX Breast Recurrence Score) that assesses the expression of 21 genes associated with breast cancer recurrence to assign women with early-stage, HR-positive, HER2-negative, axillary lymph node-negative breast cancer to the most appropriate and effective post-operative treatment.

Women in the trial who had a score in the intermediate range (11–25) were randomly assigned to receive hormone therapy alone or hormone therapy with adjuvant chemotherapy. The goal was to assess whether women who received hormone therapy alone had outcomes that were as good as those among women who received chemotherapy in addition to hormone therapy.

The rates of overall survival were also very similar in the two groups. At five years, the overall survival rate was 98.0 percent for those who received hormone therapy alone and 98.1 percent for those who received both therapies, and at nine years the respective overall survival rates were 93.9 percent and 93.8 percent.

According to the authors, the new findings suggest that chemotherapy may be avoided in about 70 per cent of women with HR-positive, HER2-negative, node-negative breast cancer:

- older than 50 and with a recurrence score of 11–25 (45 percent)
- any age with a recurrence score of 0–10 (16 percent)
- 50 years old or younger with a recurrence score of 11–15 (8 percent)

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Notes to the Editor

Cancer Trials Ireland

Cancer Trials Ireland provides people who have cancer with the opportunity to access cancer trials which may offer promising and potentially life enhancing treatments that are not yet available through the mainstream health service.

At any one time there could be in the region of 6000 patients on a cancer trial in Ireland.

Approximately 100 cancer trials are recruiting patients in 16 hospitals around the country. A further 50 trials are in the data collection and analysis stage.

Since Cancer Trials Ireland was established in 1996, more than 15,000 patients have participated in over 350 cancer trials.

Most of Ireland's Medical, Surgical and Radiation Oncologists and Haematologists are working on cancer trials. Their work is regularly presented at scientific conferences around the world.

Cancer Trials Ireland is the only organisation in Ireland which is focused solely on cancer research trials. Over 50% of all clinical trials in Ireland are cancer trials.

In May 2016 Cancer Trials Ireland published an independent report on the health and economic impacts of cancer trials in Ireland.

It found that every €1 invested in cancer trials generates €3 in savings in drugs for the HSE.

Cancer Trials Ireland works closely with local consultants and researchers, international collaborative groups such as ECOG-ACRIN, NRG, ANZUP and the main global pharmaceutical companies.

While the majority of its trials are carried out in Ireland some extend to Europe.

Cancer Trials Ireland is a not-for-profit registered charity, partly funded by the Irish Cancer Society and the Health Research Board (HRB). It also receives greatly appreciated donations from members of the public.

To find out more patients should in the first instance ask their doctor.

Details on all cancer trials open are available on **cancertrials.ie**.