

Clinical trial leads to practice changing milestone for advanced anal cancer

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Results from the first ever randomized clinical trial in advanced anal cancer patients, led and supported by The Royal Marsden NHS Foundation Trust and Cancer Research UK, in collaboration with colleagues in the US, Norway and Australia, has led to a practice changing milestone with a new approach to treatment which is safer and more effective than previously recommended treatments for this group of patients.

Published in the *Journal of Clinical Oncology* today, researchers found that a chemotherapy combination of carboplatin and paclitaxel—which is primarily used to treat other cancers, including ovarian, womb and [lung cancer](#)—performed better overall with anal cancer patients living seven months longer compared to chemotherapy treatment with cisplatin and 5-fluorouracil. These results have led to a direct change in recommended treatment guidelines in both European and American clinical practice (The European Society for Medical Oncology and National Comprehensive Cancer Network clinical practice guidelines).

Around 1,300 people are diagnosed with anal cancer each year in the UK and this number is rising by around three per cent per year. Due to small patient populations, there has previously been very limited evidence to guide treatment decisions. The findings from this study have set a new standard of care for this rare type of cancer, gaining international consensus among clinicians for the first time.

The international randomized phase II trial, led by The Royal Marsden

NHS Foundation Trust, analyzed data from 91 patients in four countries, including the UK, Norway, the US and Australia. This study was supported by the International Rare Cancers Initiative (IRCI) a global collaboration aimed at improving outcomes for patients with rare cancers. This is the first IRCI trial of its kind to complete and report its results.

This study was funded by The Royal Marsden's GI and Lymphoma Unit, the NIHR Biomedical Research Centre at The Royal Marsden and The Institute of Cancer Research, London (ICR), Cancer Research UK and The Royal Marsden Cancer Charity.

Study Chief-Investigator Dr. Sheela Rao, Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust, said:

"The results of this study have led to an immediate change in patient care. While treatment with cisplatin and 5-fluorouracil was generally considered a reasonable option for advanced anal cancer, we now know that carboplatin and paclitaxel is more effective and better tolerated. In our study, these patients lived seven months longer overall and experienced less treatment side effects.

"This is a great example of international collaboration for a rare cancer with the results having a direct impact on recommended guidelines which will benefit patients with anal cancer from around the world.

"Around 30 per cent of people with anal cancer will develop advanced disease which cannot be treated surgically, and all of these patients are eligible to receive this chemotherapy combination."

Deborah Pink, 58, was a patient on this trial who has benefitted from receiving the newly recommended chemotherapy combination. Deborah has been receiving treatment at The Royal Marsden since she was

diagnosed with anal cancer in 2011. She said:

"After my diagnosis things moved very quickly and I've had a number of different treatments, surgery and radiotherapy. When I first started this trial a few years ago, I had a complete response to the chemotherapy combination of carboplatin and paclitaxel and doctors at the Royal Marsden saw a reduction in the size of my tumor which was such positive news to hear. Being on the trial was a great opportunity and knowing the results are benefitting other patients like myself makes a real difference, it's really encouraging to know that research is being done in this area for such a rare type of cancer. Currently, I am continuing with this type of chemotherapy treatment and am monitored under the hospital with regular scans. Without this treatment and the ongoing care I've had at The Royal Marsden over the last nine years, I might not have been here."

Martin Ledwick, Cancer Research UK's head information nurse, said:

"These results clearly demonstrate the need for ongoing research so that we can continually improve treatments for people with [cancer](#). Without support for well-designed [clinical trials](#), important improvements in treatment like this can't be identified."

More information: Sheela Rao et al, International Rare Cancers Initiative Multicenter Randomized Phase II Trial of Cisplatin and Fluorouracil Versus Carboplatin and Paclitaxel in Advanced Anal Cancer: InterAACT, *Journal of Clinical Oncology* (2020). DOI: 10.1200/JCO.19.03266

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