

Immunotherapy significantly increases the number of patients free from bowel cancer: Clinical trial

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An immunotherapy drug given before surgery instead of chemotherapy meant that over ten times more patients with a certain genetic profile



were cancer-free after surgery, according to clinical trial results presented by researchers at UCL and UCLH.

The findings, presented at the <u>American Society of Clinical Oncology</u> (ASCO) Annual Meeting 2024, are interim results from the NEOPRISM-CRC phase II clinical trial assessing whether the <u>immunotherapy drug</u> pembrolizumab can improve outcomes for patients with stage two or stage three MMR deficient/MSI-High bowel cancer. The trial was a collaboration among UCL, UCLH, the Christie NHS Foundation Trust in Manchester, St. James's University Hospital in Leeds, University Hospital Southampton and the University of Glasgow.

Bowel cancer is the fourth most common cancer in the UK, with around 42,900 cases a year. Though still predominantly a cancer that affects older people, cases among the under 50s have been increasing in recent decades.

Like many cancers, if bowel cancer is caught early, the chances of a positive outcome are high. Nine in ten patients treated for stage one bowel cancer survive for five years or more, but specific sub-types of tumors don't respond as well to treatment and are more likely to return. Five-year survival falls to 65% in stage three and 10% in stage four bowel cancer.

In this trial, researchers from UCL recruited 32 patients with stage two or three bowel cancer and a certain genetic profile (MMR deficient/MSI-High bowel cancer) from five hospitals across the UK. Around 10%–15% of patients with stage two or three <u>bowel cancer</u> have this particular genetic makeup, which represents around 2,000–3,000 cases per year in the UK.

Patients were given nine weeks of pembrolizumab prior to <u>surgery</u> instead of the usual treatment of surgery and chemotherapy, then



monitored over time.

Results indicate that over 50% of patients treated with pembrolizumab had no signs of cancer after surgery. This compares to other studies where just 4% of patients treated with pre-operative chemotherapy then surgery had no signs of cancer after surgery.

All of the patients in the trial were still cancer-free many months later. The median cancer-free period was 9.7 months and ranged from 5.3 to 19 months among individual patients.

Over the next few years, the trial will also assess overall survival and relapse rates.

The approach also meant that patients did not require any post-operative chemotherapy, which has side effects and is tough to endure.

Dr. Kai-Keen Shiu, Chief Investigator of the trial from UCL Cancer Institute and a Consultant Medical Oncologist at UCLH, said, "Our results indicate that pembrolizumab is a safe and highly effective treatment to improve outcomes in patients with high-risk bowel cancers, increasing the chances of curing the disease at an early stage.

"We need to wait to see whether the patients in our trial remain cancerfree over a longer period of time, but initial indications are extremely positive. NEOPRISM-CRC is a trial that I first thought about in 2019 and am proud of my clinical and research teams at UCLH-UCL, as well as my co-investigators around the country who helped me create and deliver this study within 18 months of opening the trial in 2022. I am most of all thankful for the patients who participated in the trial so far and benefited from this treatment."

The research also assessed whether tumor mutation burden could be a



useful biomarker to predict individual risk.

Professor Mark Saunders, a Consultant Clinical Oncologist at The Christie, said, "This is a really very exciting new treatment for the 10%-15% of patients who have the right genetic makeup. Immunotherapy prior to surgery could well become a 'game-changer' for these patients with this type of cancer. Not only is the outcome better, but it saves patients from having more conventional chemotherapy, which often has more side-effects.

"In the future, immunotherapy may even replace the need for surgery. However, more trials are needed to confirm these exciting early results and The Christie is delighted to collaborate in this way so that we can offer this new form of therapy to our patients as part of the NEOPRISM trial."

Dr. Marnix Jansen, a Clinician Scientist and Consultant Histopathologist who is leading the translational research on the trial from UCL Cancer Institute and UCLH, said, "More work needs to be done to assess pembrolizumab before it could be considered <u>standard treatment</u>, but given the quality of the outcomes in this trial, I think it's possible that we could see it in the clinic within a couple of years if subsequent trials are similarly successful."

More information: Kai-Keen Shiu et al, "NEOPRISM-CRC: Neoadjuvant Pembrolizumab stratified to tumour mutation burden for High Risk Stage 2 or Stage 3 deficient-MMR/MSI-High Colorectal Cancer" will be presented at ASCO 2024 and is strictly embargoed until Sunday 2 June at 14:00 BST / 09:00 ET.



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