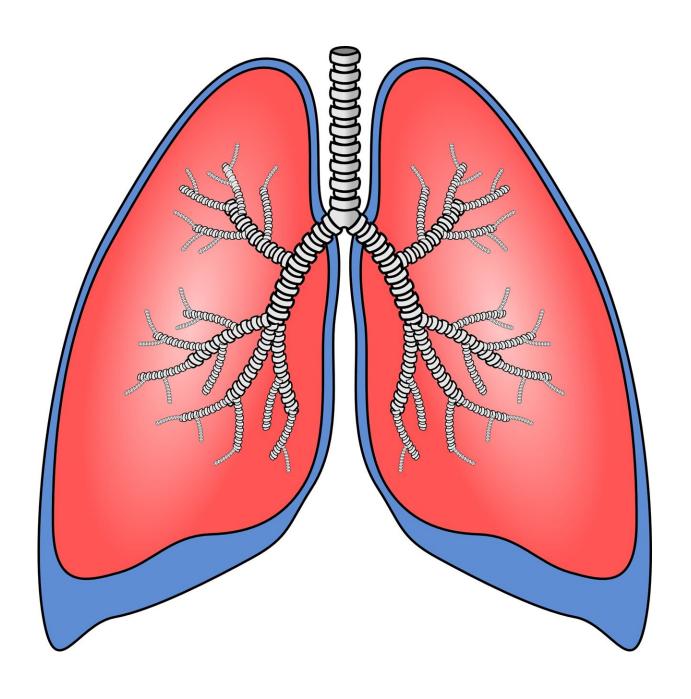


Clinical trial confirms immunotherapy drug's efficiency for treating lung cancer

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Together, the McGill University Health Centre (MUHC), the Centre hospitalier de l'Université de Montréal (CHUM) and St. Mary's Hospital Center (SMHC) have contributed to an international clinical trial that will change the way we treat non-small cell lung cancer (NSCLC)—the most common form of lung cancer.

In this trial, an immunotherapy drug called pembrolizumab (KEYTRUDA), used in conjunction with neoadjuvant chemotherapy (i.e., given before surgery) and then again after surgery, has been shown to slow <u>cancer</u> progression and recurrence and to reduce the presence of residual tumors in patients with early-stage operable NSCLC. In the experimental group, three out of five patients remained stable for two years (without cancer progression or recurrence), compared with two out of five in the control group, an improvement of around 50 percent.

The interim analysis of this randomized, double-blind, Phase III clinical trial was recently presented at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting in Chicago and published in The *New England Journal of Medicine*.

"It's an honor for me to bring the most promising lung cancer therapies to our patients by playing a leading role in the conduct of international randomized clinical trials," says Dr. Jonathan Spicer, senior author and lead surgeon of the study, medical director of the McGill Thoracic Oncology Network, scientist in the Cancer Research Program at the Research Institute of the McGill University Health Centre (RI-MUHC) and thoracic surgeon at the Montreal General Hospital of the MUHC.

"This new treatment is another important step towards improved



outcomes for patients with this common type of lung cancer. It is applicable to all patients with stage II or III NSCLC who are eligible for surgery. This represents a large number of patients on an annual basis for whom improvement in survival will be very significant."

Improving cancer survival

All patients enrolled in the trial had a surgically removable non-small cell lung cancer of stage II or III. These stages were previously associated with a survival rate at five years after diagnosis of less than 50 percent. Half of them received neoadjuvant pembrolizumab plus cisplatin-based chemotherapy followed by surgical resection and adjuvant pembrolizumab; the other half received neoadjuvant chemotherapy and surgery alone, with a placebo instead of pembrolizumab.

During the 24 months following the participants' enrollment in one of the two study groups, the investigators recorded the occurrence of undesired events such as local tumor progression that precluded the planned surgery, cancer recurrence, or death.

Out of 797 adult participants, 344 (43.2 percent) had an event or died; most of the events were disease progression or recurrence. Event-free survival at 24 months was 62.4 percent in the pembrolizumab group and 40.6 percent in the placebo group.

The trial investigators also measured the effectiveness of the treatment in reducing tumor size. A major pathological response (less than or equal to 10 percent residual viable tumors) occurred in 30.2 percent of the participants in the pembrolizumab group and in 11.0 percent of those in the placebo group and a pathological complete response (absence of residual viable tumors) occurred in 18.1 percent and 4.0 percent, respectively.



The neoadjuvant pembrolizumab did not interfere with the choice of surgical approach, the ability to undergo surgery or the incidence of surgical complications. Adverse events arising from the addition of pembrolizumab were consistent with what has been previously reported from other similar immunotherapy and surgery trials.

Montreal, an epicenter of innovation in thoracic oncology

Between the MUHC, the CHUM and the SMHC, 46 patients were recruited in the Montreal region, an outstanding achievement considering that the study was available in 227 locations worldwide. SMHC was the first center in Quebec to open the study, paving the way for other centers, and the patients enrolled at SMHC were operated at the MUHC. The CHUM was the center to recruit the largest number of patients globally.

"The CHUM and its <u>research center</u> are extremely proud to have recruited the largest number of patients of any site in this international study. The CHUM Multidisciplinary Thoracic Oncology Research and Clinical Teams work in concert to provide patients from all over the province of Quebec the latest innovations, technologies and therapies in lung cancer care. The future of lung cancer treatment is extremely bright and we will not stop investigating novel therapies until we can offer 100 percent survival to all patients," says Dr. Moishe Liberman, principal scientist and thoracic surgeon at the CHUM.

"The combination of pembrolizumab with <u>neoadjuvant chemotherapy</u> showed a significantly improved survival rate in treated patients. This is a message of hope for NSCLC patients," adds Dr. Adrian Langleben, who led the trial at SMHC.



This fruitful collaboration places Montreal among the major players in the world of randomized clinical trials in thoracic oncology.

"This work represents a major accomplishment, not only for our extremely collaborative teams in thoracic oncology, but also for our clinical trials unit at the Centre for Innovative Medicine—a fully equipped 'research hospital within a hospital' offering access to specialized staff and a full range of services for clinical research," says Penny Chipman, manager of Oncology Research at the Centre for Innovative Medicine of the RI-MUHC.

"Relying on cross-site collaboration is key to reaching as many patients as possible, and we hope to further develop strategies and partnerships to bring these trials to patients living outside of Montreal and major urban centers," says Dr. Spicer, who is also an associate professor of surgery at McGill University and an internationally renowned expert on novel therapies for patients with resectable lung cancer.

More information: Heather Wakelee et al, Perioperative Pembrolizumab for Early-Stage Non–Small-Cell Lung Cancer, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMoa2302983

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