

## Lay Summary of a Completed Research Project

<b>CCR No and Study Title:</b>	5287 CARDS - Cancer: Rapid Diagnostics and Immune assessment for SARS-CoV-2 (COVID-19)		
<b>CI and Sponsor names:</b>	Dr Sheela Rao – The Royal Marsden NHS Foundation Trust		
<b>Study opening date:</b>	26/05/2020	<b>Study closing date:</b>	29/06/2021
<b>Proposal and Objectives:</b>	<p>The COVID-19 pandemic has had a significant impact on people with gastrointestinal cancers. During the initial peak of the COVID-19 pandemic in March-April 2020 there was heightened concern of the clinical sequelae of acute COVID-19 infection in people with cancer who often have a lowered immune system. People with cancer were deemed vulnerable and at a high risk of death/poor outcome in the event of COVID-19 infection. Patients were asked to shield and were often interrupting or stopping their cancer treatment. Vaccines have been effective in reducing death and hospitalisation from COVID-19, however clinical studies did not enrol people with cancer. Therefore, the effectiveness of vaccines in people with cancer is unclear.</p> <p>The initial aim of the CARDS study was to characterise the clinical course of acute COVID-19 infection amongst people with cancer. To achieve this, we proposed to analyse nose/throat swabs and blood for clinical data from 50 people with cancer who had a recent COVID-19 infection.</p> <p>With the downturn in the incidence of acute COVID-19 due to the nationwide lockdown from March to June 2020, the goal of the study pivoted towards exploring the COVID-19 immune status amongst people with gastrointestinal cancers receiving cancer therapy. In particular, we aimed to describe response of the immune system to previous COVID-19 infection or vaccination.</p>		
<b>Main Findings:</b>	<p>Between September 2020 and April 2021, 152 participants were enrolled in the CARDS study. Approximately 500 blood samples were collected and were analysed by our collaborators at St Georges University London.</p> <p>Despite the immune suppressing effects of chemotherapy, people undergoing chemotherapy for the treatment of gastrointestinal cancers are able to mount immune responses to SARS-CoV-2 vaccines.</p> <p>The effectiveness of the vaccines is likely to wane as soon as 20-39 days and booster vaccine doses are recommended.</p>		

<p><b>Implications for practice/future research:</b></p>	<p>The results from the CARDS study will provided insights into the effectiveness of the two dose COVID-19 vaccination schedule in people with gastrointestinal cancers receiving anti-cancer therapy.</p> <p>When considering whether to have chemotherapy, people with gastrointestinal malignancies can be reassured that the immune system will produce a protective response to a COVID19 vaccination. Decreases in protective immunity are seen within 3-6 weeks of receiving the second dose of COVID-19 vaccination. Our results reaffirm the Joint Committee on Vaccination and Immunsation (JCVI) recommendations for booster doses, particular in people with weakened immune systems.</p>
<p><b>Dissemination Plan:</b></p>	<p>Results will be made available on <a href="https://clinicaltrials.gov">https://clinicaltrials.gov</a> or are available on request from the research team as per the Patient Information Sheet. They will also be published in peer reviewed scientific journals and may be presented at conferences.</p>