Government of Western Australia
North Metropolitan Health Service
Sir Charles Gairdner Osborne Park Health Care Group

Sir Charles Gairdner Hospital and Osborne Park Health Care Group

Human Research Ethics Committee

Project Summaries for Approved Projects
October to December 2020 Quarter

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Project summaries for proposals approved by the SCGOPHCG Human Research Ethics Committee – October to December 2020 quarter.

The material contained in this document is made available to assist researchers, institutions and the general public in searching for projects that have ethics approval from the SCGOPHCG HREC. It contains summaries of projects approved in the October to December 2020 quarter.

Project Title	Staff perceptions of the effectiveness of hospital wide communication during the COVID-19 pandemic.
Principal Investigator	Gemma Doleman
Institution	Sir Charles Gairdner Hospital
Approval Date	05 October 2020
The COVID-19 pandemic of 2020 has had an impact on the health and wellbeing of people across the globe. Healthcare workers are considered to be at a higher risk of distress due to the increase in work pressures, exposure to illness, long hours of work, limited resource and ethical dilemmas with allocation of healthcare resources. When staff wellbeing is not maintained, hospital integrity and patient safety are at risk. Effective communication is considered paramount in supporting healthcare staff, alleviating stress and anxiety with research showing the benefit of effective communication during past pandemics. Whilst effective communication is considered paramount, little is currently known about the effectiveness of communication with staff during the COVID-19 pandemic and the impact this has on wellbeing. It is significant to understand the effectiveness of the communication during COVID-19 and the impact that this had on staff wellbeing and ability to progress their work. Therefore, the aim of this study is to; 1) to explore staff perceptions of the effectiveness of organisational communication during the COVID-19 pandemic; 2) the impact of organisational communication during the COVID-19 pandemic on staff wellbeing and ability to progress work and patient care.	

Project Title	**ENHANCE**- A Randomized, Double Blind, Placebo controlled, Multicenter Study of Magrolimab in Combination with Azacitidine or Azacitidine Alone in Treatment-naive Patients with Higher Risk Myelodysplastic Syndrome
Principal Investigator	Carolyn Grove
Institution	Sir Charles Gairdner Hospital
Approval Date	09 October 2020
This is a randomized, double-blind, placebo-controlled multicenter study investigating magrolimab + azacitidine compared to azacitidine + placebo in previously untreated patients with intermediate/high/very high risk myelodysplastic syndrome (MDS) by Revised International Prognostic Scoring System (IPSS-R). Approximately 180 patients will be randomised 1:1 to receive either magrolimab + azacitidine or azacitidine + placebo in 28-day cycles. This will be a multicenter global study (including for example, United States and Australia). The duration of the study will be approximately up to 4 years after the last patient is randomized.	

Project Title	Evaluating the effects of a structured exercise program on melanoma patients undergoing checkpoint inhibitor therapy.
Principal Investigator	Elin Gray
Institution	Sir Charles Gairdner Hospital, Fiona Stanley Hospital
Approval Date	28 October 2020
This study aims to determine the safety and effectiveness of undergoing an 8-week telehealth (home/online) exercise program among melanoma patients who are having checkpoint inhibitor treatment. In this study physical ability tests and questionnaires will be undertaken, and participant logs completed. Most measures will be taken before and after the exercise intervention, with some questionnaires given at more frequent intervals during the study.	

Project Title	PathWest testing of samples for South African version of Australian project: Virucidal pilot study of Nasodine® antiseptic nasal spray(povidone-iodine 0.5%) in people with COVID-19 and confirmed nasal shedding of coronavirus.
Principal Investigator	Peter Friedland
Institution	PathWest (QEII)
Approval Date	02 November 2020
The goal of this trial is to measure the possibility for the 0.5% PVP-I nasal spray to be used as a nasal disinfectant to reduce the amount of SARS-CoV-2 virus residing in the nasal cavity. This is the first COVID-19 study with the 0.5% PVP-I nasal spray. If this is true, then possibly we may be able to use this spray to prevent people in close contact with COVID-19 infected people, like family members and healthcare workers, from getting COVID-19 in their nose.	

Project Title	Development and evaluation of an anticoagulant consumer education video
Principal Investigator	Leanne Chalmers
Institution	Sir Charles Gairdner Hospital
Approval Date	09 November 2020
The aim of this project is to develop a contemporary OAC consumer education video and evaluate its effect and acceptability in an Australian tertiary hospital. The evaluation phase, to be conducted at Sir Charles Gairdner Hospital (SCGH), will involve comparison of the short-term outcomes (OAC knowledge and belief about medicines) of the current verbal and written OAC education ('standard care') and video-assisted education ('video plus standard care') in consumers newly commenced on OACs. One hundred inpatients newly commenced on OAC therapy will complete a questionnaire incorporating the validated Anticoagulation Knowledge Tool (AKT) and Beliefs about Medicines Questionnaire-Specific (BMQ-Specific) before and after their education session; changes in knowledge and beliefs about medicines will be evaluated using the standard scoring systems for the AKT and BMQ-Specific. For the first 50 patients (the 'control' group), education sessions will be provided as per current 'standard care' and involve the face-to-face verbal education and the provision of written materials as necessary. For the second 50 patients (the 'intervention' group), the education session will be video-assisted, involving 'standard care' plus use of the video. The post-education survey will also evaluate the usefulness and accessibility of the OAC education session. The overall aim of the project is to provide health care professionals with a high-quality, evidence-based tool to assist in consumer education regarding OACs.	

Project Title	Improving Mesothelioma Therapy by Boosting Immune Responses to Mutations by Immunogenic Chemotherapy
Principal Investigator	Bruce Robinson
Institution	Sir Charles Gairdner Hospital, University of WA
Approval Date	03 December 2020

Clinical samples and associated clinical data from mesothelioma patients will be obtained from the National Centre for Asbestos Related Diseases Biobank. Tumour and matched normal cells from individuals will undergo comprehensive analysis to identify DNA and protein cancer–related alterations. These alterations will be evaluated using computer algorithms to predict those that are potentially immunogenic and then the top 100 of these candidates, known as neo-antigens, will be selected for downstream analysis.
Analysis of candidate neo-antigens will be performed using immune cells from the matched individual patient, including cells from longitudinally collected blood samples before and after chemotherapy. Laboratory analysis will determine which candidate neo-antigen is recognized by the patient's immune cells before and after treatment. In addition, the type, functional status and unique receptor sequence of the neo-antigen specific responding immune cells will be determined.

Project Title	Exercise medicine as chemotherapy adjunct: a multi-component program in pancreatic cancer patients receiving neoadjuvant therapy
Principal Investigator	Hao Luo
Institution	Sir Charles Gairdner Hospital
Approval Date	15 December 2020

The purpose of this research project is to investigate the feasibility and efficacy of a multi-component exercise medicine program in Pancreatic cancer (PanCa) patients receiving neoadjuvant therapy. This proposed study will be a pilot, parallel-group, randomised controlled trial. A multi-component exercise medicine program consisting of resistance training in conjunction with aerobic exercise and sport-related drills will be undertaken twice weekly in PanCa patients undergoing neoadjuvant therapy for a maximum period of 6 months. Patients will be followed-up for 6 months after the intervention period. The primary outcomes will be the overall safety and feasibility profiles including incidence and severity of adverse events, eligibility and recruitment rates of the potential participants, retention rate following study entry as well as acceptability of the intervention. In addition, the effects of the program on body composition, physical function, and patient-reported outcomes as well as on a range of clinical outcomes (such as operability rate, chemotherapy completion rate, and chemotherapy responses) will also be measured.

Project Title	Uveal melanoma archival tissue study
Principal Investigator	Elin Gray
Institution	PathWest FSH & PathWest QEII
Approval Date	17 December 2020

Uveal melanoma (UM) is a tumour emerging from the middle coat of the eye (the uveal tract). In around 50% of patients with UM, the tumour spreads to other organs, commonly to the liver through a process called metastases. Liver metastases causes the death of 90% of UM patients within 2 years**.** There is currently no effective treatment for metastatic UM, hence there is an urgent need to find and develop effective treatment for this disease.

This project will use single cell RNA sequencing to analyse the thousands of cells that form a tumour, one at a time. This will aid in the understanding of how UM tumour cells behave within metastases, and how liver cells interact with UM cells to enable the growth of the tumour. The results may reveal new ways to treat the disease by interfering with signals that allows the tumours to grow.

Overall, this project aims to analyse UM liver metastases and primary tumours archived as FFPE tissue at PathWest to validate the markers identified by RNA sequencing. In particular, researchers aim to stain FFPE UM tumours to determine the expression of specific ligands and receptors and identify the location of the cells expressing the markers within the tumour tissue and to confirm co-localisation of ligand and receptors expressing cells.

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