**Trust Sponsored Studies 2023**

**Experiences of patients undergoing hydrodistension in frozen shoulder**

IRAS ID: 307480 REC No: 22/SW/0122

Chief Investigator: Gareth Whelan – Extended Scope Practitioner (Physiotherapist) NIHR Predoctoral Clinical Academic Fellow– York & Scarborough Teaching Hospitals

Study type/area: Qualitative/Musculoskeletal/Single site/Non-commercial/Non-portfolio

The aim of this study is to explore a current gap in knowledge about the experiences of people with frozen shoulder who chose to treat the condition through hydrodistension. This will help to inform shared decision making between patients and clinicians when considering this treatment in future.

**YOGI – York Teaching Hospitals - FIT Colorectal Database – Evaluation and optimization of FIT based pathways of care: establishing a study cohort**

IRAS ID: 294969 REC No: 21/YH/0067

Chief Investigator: Professor James Turvill – Consultant Gastroenterologist – York & Scarborough Teaching Hospitals

Study type/area: Research Database/Oral and gastrointestinal/Colorectal disease and cancers/Non-commercial/Non-portfolio/Single site

The database will help to facilitate translational research; it will assemble an invaluable cohort of patients and repository of patient data that can be accessed by researchers. It will also allow patients to be contacted to access biological samples, to be invited to participate in disease specific trials, or to receive new patient information concerning their illness. The intention to build and keep a valuable and robust database of patient referrals, outcomes and permission to contact. This will amount to approximately 10, 000 colorectal patients which will provide an invaluable repository of clinical data.

**PinPoint Accuracy Study - A diagnostic accuracy study of PINPOINT blood sample analysis in detecting cancer**

IRAS ID: 311006 REC No. 22/SW/0044 NIHR Portfolio ID: 52266

Chief Investigator: Professor James Turvill – Consultant Gastroenterologist – York & Scarborough Teaching Hospitals

Study type/area: Cohort observation/ Laboratory/Cancer/Non-commercial

The study is looking at the diagnostic accuracy of the PinPoint test, a machine learning algorithm that uses a range of blood results combined with basic patient information to provide a patient risk score for cancer as;

1. A rule-out test to identify patients who have had a very low risk of cancer, to have initial management with their GP, avoiding unnecessary testing and worry on the cancer pathway
2. A predictor of patients at high-risk of cancer, to have an accelerated pathway for diagnosis

**Fast Track Faecal Calprotectin - Prospective Assessment of the Predictive Power of Faecal Calprotectin in Patients with Fast Track Colorectal Symptoms**

IRAS ID: 156515 REC No: 14/EM/0217 NIHR Portfolio ID: 30936

Chief Investigator: Professor James Turvill – Consultant Gastroenterologist – York & Scarborough Teaching Hospitals

Study type/area: Oral and Gastrointestinal/Colorectal/Cancer/Multi-centre/Non-commercial

The aim of this study is to determine prospectively the negative and positive predictive power of faecal calprotectin for organic disease in new patients referred from primary care with fast track lower gastrointestinal problems. The predictive power of faecal calprotectin for patients with colorectal cancer will additionally be assessed.

**Mother and Baby Yoga Study - Investigating the influence of an early postnatal mother and baby yoga program on mothers’ feelings about their mental health and relationship with baby: a randomized feasibility study**

IRAS ID: 294028 REC No: 22/EE/0043

Chief Investigator: Nicola Spark – Midwife - York & Scarborough Teaching Hospitals

Study type/area: Novel intervention/Randomized Controlled Trial/Non-commercial/Non-portfolio

The intended research is an eight-week online programme incorporating gentle postnatal mother and baby yoga. The online course was designed to mitigate anxieties associated with the COVID-19 pandemic, enabling women to follow the course in their own time within a safe environment. The project will provide essential pilot data to help determine whether mother and baby yoga would be beneficial if offered as a regular service.

**HES Data Haemochromatosis Study - Prevalence of cirrhosis and its related complications amongst patients with hereditary haemochromatosis (HH) in England**

IRAS ID: 324033 REC No: 23/HRA/1558

Chief Investigator: Dr Robert Driver – Consultant Hepatologist - York & Scarborough Teaching Hospitals

Study type/area: Hepatology/Data collection and analysis/Non-commercial/Non-portfolio

The study aim is to identify the proportion of HH patients with cirrhosis and cirrhosis complications such as liver cancer, fluid in the abdomen (ascites), confusion (hepatic encephalopathy), bleeding from the gut (variceal bleeding) and yellowing of the skin (jaundice).

This project will use existing population health datasets linked to Hospital Episode Statistics (HES) obtained from NHS Digital to identify HH patients. International Classification of Diseases, 10th edition (ICD10) diagnostic codes will be employed against the database to identify cirrhosis and its related complications in this cohort.

The HES database will also be used to determine independent risk factors for developing cirrhosis in the HH population and would involve reviewing factors such as diabetes, viral hepatitis infections and harmful alcohol use. This analysis will have the potential to aid the identification of HH patients most at risk of developing significant liver disease.

In addition, the study aims to review the outcomes of HH patients in different regions of England. We will also assess the duration patients have been undergoing venesection prior to developing cirrhosis to detect the proportion of HH patients who were untreated before developing serious complications.

**VOC – Breath Biomarker Detection in Patients with Suspected Breast Cancer – A pilot Study**

IRAS ID: 318636 REC No: 22/PR/1228 NIHR Portfolio ID: 54251

Chief Investigator: Jenny Piper – Consultant Oncoplastic Breast Surgeon, Lead Clinician Breast and Plastic Surgery and Trust Lead Cancer Clinician - York & Scarborough Teaching Hospitals

Study type/area: Cancer/Pilot/Non-commercial/Portfolio

Fewer than 8% of people currently referred with suspected breast cancer actually have cancer. A screening test is needed to better identify those at risk. Human breath contains within it an 'odour fingerprint' that reflects the health status of the individual, the chemicals of which are called volatile organic compounds (VOC). These can be detected in the laboratory and can act as a ‘biomarker’ to indicate abnormal processes, conditions or diseases. Our collaborators at the University of York have recently identified a VOC fingerprint in breast cancer tissue models that can be accurately and consistently distinguished from the VOC of normal breast tissue. We want to explore whether these experimental findings can be translated into clinical practice.

This pilot study will recruit patients referred to the Breast Clinic with suspected breast cancer who will then undergo breath sampling and testing. The resulting analysis will then be compared with the clinical details to establish the accuracy of diagnosis, if any. It is hoped that this pilot study will allow us to identify a breath-derived VOC biomarker screening tool for breast cancer detection. Being non-invasive and simple to capture, breath would be an attractive screening tool. The system of breath collection developed by the University is not only simple, but also quick and reproducible. It could be used in a Breast Clinic setting or a GP practice. The results of this pilot study would underpin a future research application for a formal diagnostic accuracy study, both for patients with symptoms suggestive of breast cancer, and for women using the breast screening service.

**EPDev-AI – Early phase development of an AI tool to determine disease activity in nvAMD**

IRAS ID: 276793 REC No: 22/HRA/0585

Chief Investigator: Professor Richard Gale – Consultant Medical Ophthalmologist - York & Scarborough Teaching Hospitals

Study type/area: AI/Ophthalmology/Data collection and analysis study/Feasibility-Pilot/Commercial/Non-portfolio

Age-related macular degeneration (AMD) is projected to affect an average of 1.23 million individuals by 2050. Whilst anti-VEGF treatment for neovascular AMD (nvAMD) is considered the current gold-standard care, this requires regular monitoring and treatment delivery which causes increased capacity challenges. This has highlighted the need for efficient and safe ways to diagnose and manage nvAMD. The use of artificial intelligence (AI) in medical care has the potential to alleviate some of this projected pressure facing eye clinics. Previous research has shown that AI has comparable sensitivity and specificity to clinicians in identifying ocular disorders from retinal images. The purpose of the current study was to develop and AI model to identify active from inactive nvAMD disease from retinal SD-OCT images.

**Autoflow – Data collection for the development of algorithms to predict the limits of autoregulation for cerebral and renal blood flow during major surgery with continuous invasive and non-invasive blood pressure measurements.**

IRAS ID: 290456 REC No: 20/NI/0166 NIHR Portfolio ID: 47669

Chief Investigator: Dr Simon Davies – Consultant Anesthetist - York & Scarborough Teaching Hospitals

Study type/area: Anesthesia/Perioperative Medicine and Pain Management/Single site/Non-commercial

The study will collect data about blood pressure and tissue oxygen levels and relate the two measurements. This will help to develop an algorithm to predict if oxygen levels in the brain are likely to become low in the future.

The brain regulates its own blood flow to ensure it gets all the oxygen it needs - however it can only do this when the blood pressure is between certain levels and, outside of these protective levels, brain blood flow is directly dependent on the blood pressure. Being able to predict the limit of brain blood flow autoregulation is important because low brain oxygen levels are associated with complications after surgery.

The data collected in this study will tell us if it is technically possible in the future to predict whether oxygen levels are going to be low in the brain before it happens. If clinicians have prior warning of these events, then they can potentially treat and avoid low brain oxygen levels.

**Is change in bicarb in CO2 retention faster than believed? V1 -** **Is the rate of change in bicarbonate in CO2 retention faster than previously believed? A retrospective cohort study using data from neurologically deceased patients.**

IRAS ID: 321018 REC No: 23/EE/0099 NIHR Portfolio ID:

Chief Investigator: - Dr John Berridge – Consultant Anesthetist and Intensive Care - York & Scarborough Teaching Hospitals

Study type/area: Anesthetics/Intensive Care/Neurology/Cohort Observation/Data collection and analysis study/Single site/Non-commercial/Non-portfolio

Anonymized blood gas results collected from the York and Scarborough Trust intensive care records system will be analyzed for approximately 30 patients who have been declared dead by neurological conditions. The rate of change in the rise in bicarbonate levels from the blood gas results during brainstem testing will be calculated, to see if the compensation for respiratory acidosis is faster than previously believed.

If this is the case, there are many patients who have been falsely diagnosed with chronic hypercapnia and being targeted lower oxygen saturation levels. Patients who have undergone brainstem testing have shown indications that this change is faster than believed, as during this testing, the ventilator is removed for a short period known as apnoea testing, and the CO2 measured after a period of time.