



### Trust Sponsored Studies 2025

## ColoCap – Determining the diagnostic accuracy of colon capsule endoscopy compared to standard colonoscopy in patients at risk of colorectal disease

IRAS ID: 331349 REC No: 24/NE/0178 NIHR Portfolio ID: 57318

Chief Investigator: Professor James Turvill, Professor Angus Watson

Study type/area: Interventional/Gastroenterology/Multi-site/Non-commercial/Portfolio

Early diagnosis of bowel disease is essential for the health of or population. Currently the NHS relies on colonoscopy to do this. Colonoscopy is an invasive test, painful and embarrassing for many. It is resource-intensive, requires highly trained endoscopists and expensive specialised units. Colonoscopy can miss bowel disease and it cannot be adequately completed in all. Colon capsule endoscopy (CCE) is a rapidly scalable alternative diagnostic that could transform early diagnosis. It can be performed painlessly at home making it attractive option for many. It is more environmentally sustainable than colonoscopy and can be reported by a large, trained cohort using secure web-based technology.

We conducted the evaluation of CCE as it was introduced as an emergency measure during covid and now are leading the ColoCap study to develop the evidence base to allow this disruptive technology to be implemented nationally in the near future.

#### Functional Outcome following Plate Fixation of Distal Radius Fractures

IRAS ID: 307029 REC No: 21/WA/0363

Chief Investigator: Mr Sunil Auplish

Study type/area: Observational/Orthopedic Surgery/Single site/Non-commercial/Non-portfolio

Plate fixation is a common surgical treatment option in fractures of the wrist joint (specifically, the radius). The Soong classification is a system used to grade the positioning of the plate when it is fixed to the bone. Our study seeks to identify whether different Soong classifications result in different rates of functional recovery when patients undergo plate fixation of the distal radius.

**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;



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- a) 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
- b) A predictor of patients at high-risk of cancer, to have an accelerated pathway for diagnosis

#### Daisy: Diagnostic AI System for robotic and automated triage and asses

IRAS ID: 343550 REC No: 24/YH/0138 NIHR Portfolio ID: 63764

Chief Investigator: Dr Tunde Ashaolu

Study type/area: Feasibility/Emergency Medicine/Artificial Intelligence/ Single site/Non-commercial/ Portfolio

We plan to introduce an automated triaging system called DAISY into the Emergency Department (ED) to give patients the opportunity to self-direct their initial consultation. This is a new system in development, with a robot like the image at the top of this sheet, a touchscreen that will ask patients a number of questions about their current health (as a Triage nurse or doctor in the Emergency Department may do) but also with some attached devices (like a blood pressure monitor and thermometer) that patients can use to help DAISY assess patients' current health.

Our study aims to demonstrate how patients can interact with the automated system to produce a report that is useful for the doctors and nurses in the ED. We will examine the duration and timeliness of the automated assessment to see if it frees up staff time and we will see how patients find the experience of using the DAISY system.

#### MenSH-IBD

IRAS ID: 334340 REC No: 24/EE/0158 NIHR Portfolio ID: 58565

Chief Investigator: Sara Ma

Study type/area: Interventional/Inflammatory Bowel Disease/Non-commercial/Portfolio

This research aims to develop an intervention to help nurses improve the assessment and care of the sexual health needs of men with Inflammatory Bowel Disease (IBD). This is a long-term digestive condition that is often diagnosed between the ages of 15-30 years. Patients often have bloody diarrhoea, abdominal pain, incontinence, and fatigue. When severe, the disease can lead to hospital admission and surgery. There is growing recognition that IBD can negatively affect sexual health and impact on patients' relationships and quality of life, but men's needs have been neglected in research. Men report that their sexual health is rarely discussed at NHS IBD clinic appointments, and specialist information and support are lacking. In this study we will work with patients, their partners, nurses, and other healthcare professionals to develop a nursing intervention that addresses this unmet need through information, assessment, and support. This study consists of three main parts which have been labelled workstreams. In Workstream One we will identify how the sexual health of men with IBD is currently assessed and cared for in the NHS using three large scale surveys that will include; (1) NHS Trusts (2) Nurses (3) People with IBD. In Workstream Two we will gather ideas on appropriate ways to improve the healthcare of men with IBD by conducting interviews with men with IBD and partners of men with IBD.





We will also conduct focus groups with healthcare professionals to hear their ideas of how services can be improved. In Workstream Three we will hold a series of workshops with patients and healthcare professionals to develop an intervention and consider how and why it could help patients. The design of the study has been developed with a patient advisory group and input from IBD health professionals.

#### York and Scarborough PAD Research Database

IRAS ID: 328152

Chief Investigator: Mr Andrew Thompson

Study type/area: Data collection/ Vascular Medicine/Non-commercial/Non-portfolio

Peripheral Artery Disease (PAD) is a common circulatory disorder that affects millions of people worldwide, causing significant morbidity and mortality. PAD is characterised by the narrowing or blockage of blood vessels, primarily due to atherosclerosis, leading to reduced blood flow to the extremities. The two primary manifestations of PAD are intermittent claudication (IC) and critical limb ischemia (CLI). Establishing a research database for patients with **symptomatic PAD** will provide valuable insights into the disease process, management, and outcomes for these patients. The main objectives are:

1. To collect comprehensive clinical, demographic, and laboratory data from patients with symptomatic PAD, providing a rich dataset for investigating disease mechanisms, risk factors, and outcomes.

2. To enable longitudinal data collection, allowing for the study of disease progression, treatment effectiveness, and long-term outcomes in patients with symptomatic PAD.

3. To facilitate collaboration among researchers and healthcare professionals by providing a centralised, secure platform for sharing and analysing data.

4. To support hypothesis-driven and exploratory research by offering access to diverse patient data and fostering a culture of data-driven decision-making.

5. To inform the development of targeted interventions and treatment strategies for patients with symptomatic PAD by providing insights into disease patterns, patient characteristics, and treatment outcomes.

#### Predictors of poor outcomes and mortality in major trauma patient

IRAS ID: 354257

Chief Investigator: Dr Bahir Almazedi

Study type/area: Data Collection/Trauma/Non-commercial/Non-Portfolio

Traumatic injury is a global burden and contributes significantly to death and disability across the UK. For every trauma death, at least 2 people are left with severe and permanent disability and the effects of traumatic injury have considerable long-term implications on the quality of life of its survivors. As a result of traumatic injury, there is also a significant impact upon the associated costs to the NHS. Major trauma is the term used to describe serious and often multiple injuries that could cause permanent disability or death. Trauma has a bimodal age distribution with the first peak in the under-20s and then the second peak in the over-65 age group. It is the biggest killer of people aged below 45 years in the UK and in those people that survive a traumatic injury;



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a large number will have permanent disabilities. The estimated costs of major trauma are between £0.3 and £0.4 billion a year in immediate treatment. The cost of any subsequent hospital treatments, rehabilitation, home care support or informal carer costs are unknown. The National Audit Office estimated that the annual lost economic output as a result of major trauma is between £3.3 billion and £3.7 billion. The National Audit Office (2010) report estimated that there are 20,000 cases of major trauma per year in England; 5,400 people die of their injuries with many others sustaining permanent disability. Every trauma death costs the nation in excess of £0.75 million and every major injury £50,000. (1). Improving outcomes and preventing death of major trauma patients will have huge health and economic benefits at a local and national level, and trauma care research will help towards achieving this. Understanding which patients are at risk of poor outcomes following traumatic injury can help in developing system and clinical management guidelines to drive improvements in clinical safety and patient outcomes.

### Assessing aetiological cofactors for cirrhosis and hepatocellular carcinoma in patients with hereditary haemochromatosis who have undergone liver transplantation

IRAS ID: 328890 REC No: 23/HRA/5121

Chief Investigator: Dr Prabhsimran Singh

Study type/area: Data collection/Hepatology/ Non-Commercial/Non-portfolio

The study aims to retrospectively review all Hereditary Haemochromatosis patients who have undergone liver transplantation for cirrhosis and/or Hepatocellular Carcinoma in the UK over the past 15 years to establish the presence of additional risk factors for cirrhosis in this population that may have accelerated their liver disease progression.

## Assessment of cofactors for liver fibrosis among patients with hereditary haemochromatosis

IRAS ID: 332667

Chief Investigator: Dr Robert Driver

Study type/area: Data collection/Hepatology/ Non-Commercial/Non-portfolio

The study aims to retrospectively review Hereditary Haemochromatosis patients currently being managed in secondary care in the Yorkshire region to assess the presence of cofactors for liver fibrosis and its association with transient elastography (FibroScan) scores.

In addition, we will also assess the proportion of Hereditary Haemochromatosis patients who have had a transient elastography completed which is now recommended by the EASL 2022 haemochromatosis guidelines. The use of other non-invasive liver fibrosis assessments such as FIB-4, ELF and APRI will be noted as well. As part of the study, we will also be able to evaluate the prevalence of cirrhosis and HCC in the study population.



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