Respiratory research

taking place at North Bristol NHS Trust.

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R&D No	Project Title	Project Description
1963 End date: 31/12/2020	Investigation of Pleural Disease: Improving the Patient Pathway 1	Investigation of pleural disease: improving the patient pathway 1
3172 End date: 15/02/2022	BTS IPF and Sarcoidosis Registry	British Thoracic Society Interstitial Lung Disease Registry Project
3201 End date: 01/03/2021	ILD Genetics	ILD Genetics - Identification of disease susceptibility genes and autoantibodies associated with the development and clinical characteristics of interstitial lung disease (ILD) in patients with and without proven connective tissue diseases (CTDs).
3303 End date: 30/06/2021	LungCAST	Smoking causes around 85% of lung cancer. Continued smoking after diagnosis probably worsens survival and increases treatment complications in lung cancer but prospective, well-designed studies are lacking. This project is an observational cohort study recording clinical outcomes in smokers, never-smokers, and ex-smokers newly diagnosed with lung cancer. I, using exhaled carbon monoxide (eCO) to validate smoking status when they attend for further lung cancer clinics. This project is unique, as every patient with a clinical diagnosis of lung cancer will have their smoking status biologically validated by a quick and easy test (eCO). eCO will be further validated by measuring urinary metabolites of nicotine in a sub-set of patients. Those enrolled will also complete a generic quality of life questionnaire at regular intervals. These research appointments will coincide with other routine hospital appointments wherever possible, and survival status will reported up to 24 months after enrolment.
3598 End date: 31/03/2019	Randomised Ambulatory Management of Primary Pneumothorax	RAMPP is an interventional multi-centre (UK only) randomised controlled trial comparing ambulatory to standard (in-patient treatment with aspiration/chest drain) management of primary pneumothorax. Primary outcome is total hospital stay

	(RAMPP)	up to 30 days post-randomisation.
3607 End date: 01/06/2019	HI-SPEC	Heimlich Valves In Secondary Spontaneous Pneumothorax: Enhancing Care (HI-SPEC) A pneumothorax is a collection of air around the lung within the chest which can be due to an injury puncturing the lung or due to a leak of air from the lung. A leak of air from the lung can occur spontaneously in patients without lung disease (Primary spontaneous pneumothorax) or in patients with known previous lung disease (Secondary spontaneous pneumothorax). When a pneumothorax occurs, the lung collapses often causing breathlessness and chest pain. The treatment of a pneumothorax frequently involves a tube being inserted into the space around the lung to allow the air to escape and the lung to inflate again. The tube inserted in the space around the lung is usually connected to an `underwater seal' with the tip of the tube in a bottle of sterile water. This allows air to escape from the chest by bubbling through the water. An alternative device is a Heimlich valve, which is an enclosed valve connected to a chest tube. Studies have shown that Heimlich valves can be useful for the treatment of pneumothorax and may allow patients to be treated at home. For patients with lung disease and secondary spontaneous pneumothorax there are studies suggesting that these valves are safe and have some advantages, but there are no trials directly comparing them against standard treatment. This study will randomly allocating patients with secondary spontaneous pneumothorax to a Heimlich valve or to an underwater seal, in order to allow a fair comparison. The study will particularly assess how long patients are in hospital for, patients' quality of life, levels of chest pain and breathlessness, how many other procedures are required for treatment, whether surgery is needed and readmissions to hospital. We will also assess if treatment affects pneumothorax happening again, or any problems related to the procedures.
3807 End date: 30/04/2020	Detection of genomic mutations in blood and urine free circulating tumour DNA	Detection of genomic mutations in blood and urine free circulating tumour DNA (ctDNA) in inoperable and metastatic lung adenocarcinoma harbouring an EGFR mutation on tissue. This is an observational/non-interventional study to assess the feasibility of detecting EGFR mutation on blood and urine sample of patients with adenocarcinoma known to have an EGFR mutation on the tissue sample.

3850a End date: 05/04/2027	ASSESS-Meso (TILT) Cohort Study	A prospective observational cohort study examining the natural history of mesothelioma, exploring potential biomarkers and factors that may predict outcome, as well as providing a resource for future trials within a cohort. TILT Cohort study
3850b End date: 01/08/2018	The TILT Trial - RCT	Mesothelioma is an aggressive cancer that affects the lung lining. It is incurable, and there is only one effective chemotherapy, which extends life by just three months. New treatments are desperately needed. One potential treatment targets the immune system. A healthy immune system identifies and attacks cancer cells, but mesothelioma hides from protective immune cells, and therefore escapes attack. Our research will use a "dead" bacteria, called OK-432, to stimulate immune cells to attack the mesothelioma. This may help people live longer with mesothelioma. TILT is a feasibility study using the trial within a cohort design. The design allows us to embed the trial in an existing cohort study, called ASSESS-meso. Participants in ASSESS-meso have agreed for their information to be used to identify clinical trials they may be suitable for, and to be randomly selected to join those trials. We will identify 45 people who are suitable for TILT, and randomly select 25 of them to receive OK432. They will be asked to consent to receive a single dose of OK432, delivered via an indwelling pleural catheter. The 20 participants who are not selected will continue follow-up in ASSESS-meso, receiving usual care. They will provide control data for TILT, having given prior consent for their information to be used in this way. They will not be told about OK432 as, in real life, patients are not told about treatments that they do not receive. This potentially reduces disappointment in the observational arm, as mesothelioma patients often join trials hoping to receive new treatments. At the end of the trial we will assess the feasibility of the methodology, based on recruitment rates, uptake of OK432 and data completeness rates. We will also interview participants and their relatives to explore the acceptability of the trial design to them.
3950 End date:	Idiopathic Pulmonary Fibrosis Job Exposures Study	Idiopathic pulmonary fibrosis (IPF) is a scarring lung disease. It damages the air sacs that allow oxygen to be transferred into the blood and transported to vital organs. These changes

31/10/2019	(IPF JES)	make people with IPF cough and feel short of breath. We don't know what causes the damage. People who get IPF are usually older than 40; it's a very serious illness that cannot be cured and gets worse over time. Statistics show that IPF is becoming more common in the UK but it's not known why. It can be difficult for doctors to tell if someone has IPF or another disease called asbestosis. Asbestosis is like IPF but different because we know that breathing in asbestos dust has caused the lung damage. Our study will help to find out how much IPF is due to breathing in asbestos at work. This will help us to understand IPF, make sure people get the right treatment and compensation they are entitled to, and make sure that the rules about asbestos dust at work are right so that we protect workers and prevent disease in the future.
3974 End date: 30/09/2019	MesoTRAP Feasibility Study	Malignant pleural mesothelioma is a cancer, caused by asbestos, affecting 2500 UK patients each year. The main symptom is breathlessness caused by fluid building up in the space between the lung and the chest wall. Treatment involves draining fluid to allow the lung to re-expand. However, sometimes tumour growing over the surface of the lung prevents it from re-expanding. This 'trapped' lung results in fluid re-accumulation and repeated drainage leading to significant patient distress and multiple hospital visits. One approach to dealing with 'trapped' lung in mesothelioma is to insert a thin tube (Indwelling Pleural Catheter) into the space around the lung. The tube can stay in place for a long time allowing patients to drain off fluid at home. The other approach is a keyhole surgical operation to remove as much tumour as possible from the lining of the lung to allow it to re-expand. We do not know which of these two approaches is more effective at relieving breathlessness. We want to undertake a study to find out which approach is best. First, we need to do a small study to determine whether we can recruit 38 patients in 18 months. We will collect information on how common 'trapped' lung really is and examine quality of life before and after treatment as well as safety aspects. A sub-study will find out what patients think about the study in order to improve how we run the full-scale study. We will make our findings known through patient support

		groups, scientific journals, national and international conferences. The results will be used to decide whether a larger study should be done.
3993 End date: 30/06/2019	CC-90001-IPF-001 - Safety & Efficacy of CC90001 In Patients With IPF	A Phase 2, 24-week, randomized, double-blind, placebo-controlled, multicentre study, followed by a 24-week extension, to evaluate the efficacy and safety of CC-90001 in subjects with Idiopathic Pulmonary Fibrosis
4019 End date: 30/09/2019	Evaluation of CPET use in IPF	Evaluation of Cardio-Pulmonary Exercise Testing (CPET) as a prognostic tool in patients with Idiopathic Pulmonary Fibrosis (IPF) Personalised medicine is a medical approach that emphasises the customisation of healthcare, with all decisions and practices being tailored to individual patients. Idiopathic pulmonary fibrosis (IPF) is a progressive fibrosing condition of the lungs with a median survival of 2-3 years from diagnosis. There is however vast heterogeneity in terms of presenting features, severity, disease course and thus individual survival which leads to difficulties for patients and clinicians in terms of end of life discussions, treatment choices and conduct of clinical trials. Clinicians would benefit from tools that would help to better predict clinical progression or track response to therapy. Several prognostic tools have been used in IPF with variable success. Cardio-Pulmonary Exercise Testing (CPET) has been proposed as potentially effective tool for the early detection of gas exchange abnormalities but its prognostic value remains uncertain. There is limited data available on the use of CPET as a predictive tool for disease progression in the setting of IPF, with a weak correlation between CPET and mortality reported in small cohorts. The predictive value of CPET in determining future disease progression and its relationship with Quality of Life (QoL) measurements, lung physiology and 6-minute walk testing (6MWT) remains uncertain. We aim to investigate predictive use of CPET in determining future disease progression in IPF and its relationship with existing proposed biomarkers, QOL measures, lung physiology and 6MWT.
4076 End date: 01/08/2020	UK Lung Volume Reduction - multicentre	Many people with chronic obstructive pulmonary disease (COPD) remain very breathless and limited. In some patients, with the appropriate pattern of emphysema, an operation

	observational	called lung volume reduction surgery is effective at removing the worst affected area of lung. New techniques have been developed where emphysema can be treated using a fibre-optic camera called a bronchoscope. Trials have shown that using a bronchoscope to place endobronchial valves into the airways can be very effective in carefully selected patients and the technique is now being adopted in hospitals across the UK. This study will collect data from people undergoing these procedures at hospitals across the UK to evaluate how well they work in practice and what factors at baseline influence response. Baseline, three month and 12 month follow up data will be collected. This will include lung function data, measures of exercise capacity, questionnaires about health status and CT scan results. Questions addressed will include: (1) What lung function improvement is seen in clinical practice? (2) What factors determine who is most likely to respond? (3) How safe are the procedures and what is the rate of complications? (4) What proportion of people undergoing bronchoscopic procedures require repeat procedures or surgery subsequently? (5) Does long term survival differ between people undergoing the different treatments? The study is supported by The British Lung Foundation and sponsored by Imperial College, London. By building collaboration, the establishment of the network will also produce a structure that will make evaluation of future bronchoscopic techniques easier bringing innovative treatments into play more quickly.
4094 End date: 01/04/2020	Bristol Interstitial Lung Disease (B-ILD) Tissue Collection	Investigation into the use of genetic factors and biomarkers to phenotype patients with Interstitial Lung Disease (ILD): Bristol Interstitial Lung disease Tissue Collection (B-ILD-TC) Interstitial Lung Disease (ILD) is the umbrella term used to describe a group of related diseases where there is progressive damage to the lung and replacement of healthy tissue with fibrotic/scarred tissue. Biomarkers have the potential to help discriminate between health and disease but also disease severity and response to therapy. Clinicians would benefit from bedside tools that would help us better understand who to treat, when to treat

		and which patients are likely to respond best to novel high cost drugs developed for this field. This study aims to evaluate whether we can use biomarkers or genetic factors in the clinical setting to help inform patients of their prognosis or to direct us on which patients are most likely to benefit from existing treatments.
4183 End date: 14/09/2021	TRAIL1	A randomized, double-blind, placebo-controlled, Phase 2 Study of Safety, Tolerability and Efficacy of Pirfenidone in patients with Rheumatoid Arthritis Interstitial Lung Disease
4198 End date: 01/05/2019	BASIC	A randomised, controlled trial of the use of a dedicated ballooned intercostal drain The use of a tube inserted between the ribs (intercostal drain) to remove air or fluid from around the lung is an essential tool in the management of respiratory patients. A common complication of drain insertion is accidental removal of the drain, usually as a result of inadequate securing techniques. This often results in the need for further medical or surgical procedures (including drain re-siting), with associated additional risk to the patient and an increase in health care costs. One suggested method to reduce premature drain removal is to use intercostal drains with ballooned tips. The balloon would then provide a relatively atraumatic physical obstruction to the drain insertion site. A small trial of the new drains suggested that there was a reduced need for further procedures without causing any additional discomfort or problems. We propose a randomised controlled trial (i.e. patients are randomly assigned to either the new treatment or to standard care) of a dedicated ballooned intercostal drain to investigate whether a reduction in drain re-siting rates can be achieved. Pain scores will also be assessed during this trial to ensure that irritation of the lining of the lung and chest wall is not prohibitive.
4205 End date: 31/05/2019	Effect on HRCT Endpoints to Glucocorticoid in Pulmonary Sarcoidosis	A multi-centre, open-label study to estimate the effect sizes of HRCT endpoints in response to Glucocorticoid induction therapy in subject with Pulmonary Sarcoidsis
4224 End date: 30/09/2020	MARS 2	Mesothelioma is a cancer of the thin membrane that lines the chest and abdomen. Around 2300 people in the UK are diagnosed with mesothelioma each year and the average

		survival is approximately 17 months. Exposure to asbestos is the most common cause although the cancer does not usually become apparent until 30-40 years after exposure. Anti-cancer drugs (chemotherapy) are usually given to help treat mesothelioma and sometimes lung-sparing surgery (pleurectomy decortication) surgery is undertaken. However, it is not known if this surgery, in addition to chemotherapy, can increase survival and improve the quality of life for patients. The aim of the MARS2 study is to determine if it is feasible to enrol patients with mesothelioma into a study randomising them to chemotherapy only or chemotherapy and lung-sparing surgery.
4414 End date: 01/12/2019	The Meso-ORIGINS Feasibility Study	MPM typically develops 30-50 years after inhalation of asbestos fibers and is often presaged by radiological and/or clinical evidence of asbestos-related chronic pleural inflammation, and frequently by overt pleural effusion. The base agnostic pattern of DNA damage recently reported in MPM also suggests a prominent role for immune or inflammatory triggers. However, the recent genomic characterisation of MPM (1) poses major questions regarding the pressures that drive MPM evolution, being dominated by loss of tumour suppressors, with few protein-altering mutations in known oncogenes (1). Greater understanding of the driving (oncogenic) +/- permissive (immunological) events is required to design effective MPM treatments. In a future study called Meso-ORIGINS, we aim to define in vivo the key biological events that drive or permit evolution of MPM. Meso-ORIGINS will involve serial biological surveillance (using a protocol involving circulating markers, imaging +/- repeat pleural fluid and biopsies) over a 2-year period preceding the diagnosis of MPM. This will be achieved by recruiting approx. 850 patients with Benign Asbestos Pleural Effusion (BAPE), of whom an estimated 12% (n=100) will develop MPM based on previous data (2). This will facilitate unprecedented surveillance of the key early biological events in MPM tumorigenesis. These will be interrogated for mechanisms and potential druggable targets in a genetically engineered mouse model (GEMM) integrated into the Meso-ORIGINS program. The current feasibility study will address important areas of uncertainty regarding the current Meso-ORIGINS design, including the technical feasibility and patient acceptability of

		the proposed surveillance protocol (including repeat Local Anaesthetic Thoracoscopy (LAT)) and the sample size estimate.
4424 End date: 27/01/2020	OPTIMUM Trial	Randomised controlled trial comparing outpatient management of malignant pleural effusion via an indwelling pleural catheter and talc pleurodesis versus standard inpatient management in improving health related quality of life.