involves participants writing about a stressful or traumatic event for 15-20 minutes on 3-5 consecutive days. It has been associated with improvements in psychological (e.g. Quality of Life) and clinical (immune function) outcomes in breast cancer patients. This study, funded internally by King's College London, will assess whether expressive writing has a positive effect on psychological outcomes in patients undergoing haemodialysis. Contact details: **Rachel.Hilton@gstt.nhs.uk**

Studies in 'acute kidney injury' Acute kidney failure is a serious problem. There are several reasons why kidneys may fail. In some patients, kidney failure is caused as a side effect of common medications like painkillers or antibiotics. However, it is not clear why some people develop kidney problems after taking certain drugs and others don't. It is assumed that genetic risk factors play a role. Together with experts from other countries, the team at GSTT is trying to identify the genetic factors for kidney problems caused by medications. We hope that a better understanding of the role of genetics will allow us to select drugs for patients better. Anyone who has had sudden kidney problems from medications can take part. The study is funded by The international Serious Adverse Event Consortium (iSAEC). Contact details: **Marlies.Ostermann@gstt.nhs.uk**

Biomarker studies in kidney transplant rejection. Biomarkers are clinical tests that predict what will happen to the transplant, sometimes months or years in advance. KALIBRE is trying to develop an early warning signal that identifies patients at risk of acute rejection, so that rejection can be prevented. It is funded by Guy's Charity and the MRC. Contact details: **maria.hernandez@kcl.ac.uk;** or **Paramit.Chowdhury@gstt.nhs.uk**

DECISIONS is designed to incorporate transplant patients' preferences into the development and application of a biomarker test to identify those who may be tolerant of their graft. As these tests are never completely accurate we are examining what level of risk patients are willing to take in following biomarker led care, and to explain variations in risk preferences by identifying the social, medical and contextual factors that are involved in their decision-making process. The level of risk is measured by a novel modified Standard Gamble task. This research is funded by Guy's Hospital and the NIHR BRC at Guy's and St Thomas' NHS Foundation Trust and King's College London. Contact details: **irene.rebollo_mesa@kcl.ac.uk** or **jean.harrington@kcl.ac.uk**

Defining the pathogenic role of cellular immune responses to alcohol dehydrogenase in severe alcohol-related liver disease
One third of people who drink to excess develop alcoholic hepatitis (AH), characterised by hepatic inflammation, liver failure and death within 28 days in 35% of patients. Others develop alcohol-related cirrhosis (ARC), with an insidious onset of liver failure. The pathological mechanisms underpinning

AH and ARC remain poorly understood. Our group has demonstrated that patients with ARC have antibodies directed to alcohol dehydrogenase (ADH), associated with disease severity and active alcohol consumption. We are now recruiting patients with AH to determine the role of cellular immunity to ADH in the pathogenesis of AH. The trial is funded by The Wellcome Trust. Contact details: **laura.blackmore@kcl.ac.uk** or **yun.ma@kcl.ac.uk**

SIMULATion in Enhancing patient Safety
The SIMULATES study hypothesises that simulation based learning improves surgical skills and benefits patients by ensuring safer clinical practice. The objectives are to: 1. Evaluate effectiveness of learning and teaching methods in simulated environments using qualitative methodology; 2. Study the effect of simulation training on learning curves and to investigate whether simulation training reduces the initial phase of the learning curve; 3. Study the association between technical skills (TS) and non-technical skills (NTS) using observational tools within the operating theatres (both in simulated and hospital environments); and 4. Conduct economic analysis of impact of simulation on urological training by measuring difference in direct & indirect costs associated with training. This study is funded by The Urology Foundation (TUF) and will start recruiting participants nationally from August 2014 onwards. Contact details: **prokarurol@gmail.com**

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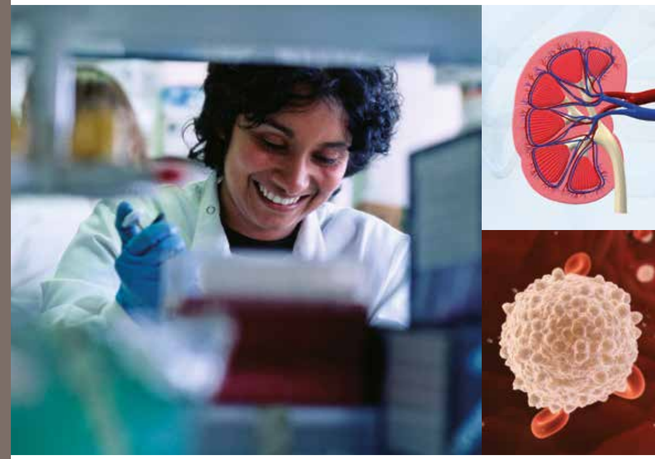
KING'S College LONDON

Interventional and observational studies in kidney and liver diseases and transplantation



KING'S HEALTH PARTNERS

Pioneering better health for all

EMPIRIKAL A UK multicentre randomised controlled trial of a novel anti-inflammation drug, called Mirococept, developed within the MRC Centre for Transplantation. This belongs to a new class of drug, designed to 'paint' the inside of kidneys before transplantation, to protect from immediate damage caused by the immune system. The trial hopes to show that, compared to kidneys prepared for transplantation in the standard way, the addition of Mirococept allows more kidneys to function normally within the first week. The trial is funded by the MRC and is led by researchers from Guy's Hospital. Contact details: **Martin.Drage@gstt.nhs.uk**

ReMIND A UK multicentre randomised controlled trial designed to test whether a drug called Rituximab, given intravenously before transplantation, can allow successful transplantation to be performed using reduced amounts of conventional immunosuppressive drugs, and ultimately improve the long-term health and well-being of both the transplant and the patient. Rituximab is expected to protect the kidney against rejection, at the same time as minimising the number of tablet drugs normally used. The trial is funded by Guy's Hospital and Astellas Pharmaceuticals and led by researchers from Guy's Hospital. Contact details: **Nizam.Mamode@gstt.nhs.uk**

The ONE Study An international multicentre randomised controlled clinical trial to test the safety and effectiveness of cell therapy in kidney transplant recipients. The cells in question are white blood cells that regulate the immune response against the kidney. Cells will be isolated from the kidney recipient prior to transplantation and grown under sterile conditions in a new, specially constructed unit at Guy's Hospital (who will supply cells to all sites in the UK). They will be re-injected back into the patient 5 days after their transplant. If they are shown to reduce the immune response against the kidney, patients will have the doses of their drugs reduced, with the hope of preventing the side effects of immunosuppression. The trial is funded by the European Union and coordinated by researchers in Germany. Recruitment is now open; contact details: **Rachel.Hilton@gstt.nhs.uk** or **David.Game@gstt.nhs.uk**

OuTSMART A UK multicentre randomised controlled trial to identify and treat established kidney transplants that are at risk of developing problems and of failing more quickly than average. It builds upon the knowledge that a biomarker called 'HLA antibodies', which can be detected in the blood, identifies patients at risk of these problems, and will test the idea that optimising the doses of new immunosuppressive drugs can prevent these problems from developing and prevent transplants from failing. The trial is funded by the NIHR and is led by researchers from King's College London at Guy's Hospital. Contact details: **anthony.dorling@kcl.ac.uk**

RituxiCAN-G4 A UK multicentre randomised controlled clinical trial to test whether Rituximab can stabilise kidney function in patients with a 'smouldering' type of rejection, after conventional best-available immuosuppressive drugs have failed. Existing evidence suggests Rituximab might work, but the trial will also assess how safe it is in renal transplant patients. The trial is funded by King's College London and Guy's Hospital and is led by researchers from King's and Guy's. Contact details: **anthony.dorling@kcl.ac.uk**

Trials of Eculizumab in patients at very high risk of rejection Guy's Hospital is a national centre for patients who are at very high risk of rejection, because they have antibodies against kidney transplants. These types of patients wait longer for a transplant allocated in the normal way, but Guy's has developed ways of circumventing the antibodies to allow a transplant to proceed. However, these types of transplant are still at risk of severe rejection. Eculizumab is a new type of drug that inhibits part of the immune system ('complement') involved in severe rejection. We are participating in two international multicentre randomised controlled trials of this drug in these patients, one for those with living donors and the second for those accepting kidneys from the national organ register. The trial is funded by Alexion Pharmaceuticals. Recruitment is now closed. Contact details: **Nizam.Mamode@gstt.nhs.uk**

POWAR A UK multicentre randomised controlled clinical trial designed to test whether routine use of a single dose of intravenous antibiotics can prevent serious infections developing in living organ donors after removal of a kidney for transplantation. These patients are usually fit and healthy, and modern surgery techniques mean they spend less time in hospital after donation compared to several years ago. The risk of infection after operation has to be balanced against the risk of promoting resistant bugs if antibiotics are used inappropriately. The trial is funded by the NIHR and is led by researchers from Guy's Hospital. Contact details: **Nizam.Mamode@gstt.nhs.uk**

Clinical study of MCMV5322A/MCMV3068A in kidney transplant recipients at high risk for CMV disease An international multicentre randomised controlled trial of an experimental drug in kidney transplant patients to prevent infection from a virus called cytomegalovirus (CMV). CMV can cause fever and fatigue, and can damage important organs, including the transplant. In this study, patients will get either placebo (a non-active substance) or the active study drug. The trial hopes to show that this new drug is safe and effective. The trial is funded and sponsored by Genentech pharmaceuticals. Recruitment has now closed but trial participants remain under active follow-up. Contact details: **Rachel.Hilton@gstt.nhs.uk**

RIFSYS A placebo-controlled double-blind randomised trial to investigate the efficacy of Rifaximin versus placebo in improving systemic inflammation and neutrophil malfunction in patients with cirrhosis and chronic hepatic encephalopathy. Patients with liver cirrhosis are particularly at risk of getting bacterial infections, and these can lead to complications such as hepatic encephalopathy (HE). This affects brain function and can cause symptoms that range from changes in personality to altered memory, concentration, or even loss of consciousness, affecting quality of life in a major way and often leading to hospital admission, and sometimes even the need for liver transplantation. This study aims to assess an antibiotic called Rifaximin to measure how it affects those processes that are thought to be important in the development of HE. These include the immune function and changes in gut bacteria and overall gut 'leakiness'. The trial is funded by Norgine UK Ltd and will be recruiting from mid-2014 for 12 months. Contact details: **hye-jeong.lee@nhs.net**

ORGANOX A multicentre randomised controlled trial to compare the efficacy of ex-vivo normothermic machine perfusion with static cold storage in human liver transplantation. The standard method of storing and transporting a liver for transplantation is to perfuse with a cold perfusion solution and store the liver in an ice box. To optimise the condition of such higher risk organs there is increased interest in continuous perfusion of the organ with blood at normal body temperature (normothermic perfusion). Livers will be randomly allocated to static cold storage (control group) or normothermic machine perfusion using the OrganOx metra device (study group). Recipients will then undergo transplantation and be managed according to standard local protocols. The two groups will be compared to investigate the potential benefit of normothermic machine perfusion. The trial is funded by the European Union Seventh Framework Programme (FP7): the COPE study (Work Package WP2). Contact details: **wayel.jassem@nhs.net**

Thril A single centre 'first in human' pilot study evaluating the safety & effectiveness of a cell therapy in liver transplant recipients. Regulatory T cells are white blood cells that regulate the immune system against the liver transplant. These cells will be taken from the patient before transplantation and grown in a purpose built laboratory at Guy's Hospital to increase their number. The cells will then be re-injected into the recipient 3 months after transplantation, with the hope that the liver will be accepted without the need for medication. The drugs will slowly be withdrawn 12 months after transplantation with the aim of avoiding the long-term side effects of these medications including diabetes, high blood pressure and heart disease. The trial is funded by the MRC, supported by the NIHR Biomedical Research Centre and led by researchers at King's College London and King's College Hospital. Contact details: **sanchez_fueyo@kcl.ac.uk** or **giovanna.lombardi@kcl.ac.uk**

Observational Studies

ATTOM Kidney and pancreas transplantation are gold standard treatments for patients with kidney failure and type 1 diabetes respectively, because transplantation extends and improves the quality of life in suitable patients. However, there is wide variability in access to transplantation across the UK (i.e. a post code lottery), due to factors that are poorly understood. This UK multicentre observational study, led by researchers from Cambridge, explores the reasons behind inter-centre variability and will develop tools to maximise transplant outcomes in the UK. Recruitment has now closed but trial participants remain under active follow-up. Contact details: **Rachel.Hilton@gstt.nhs.uk**

Outcomes after living donation Living kidney donors undergo surgery for the benefit of others. The aim of this study is to investigate the psychosocial aspects of living donation with view to understanding both positive and negative outcomes after surgery. The study will use qualitative in-depth interviews, questionnaires and a national survey. Long-term, the results will improve the support and care offered to donors before and after their surgery. This study is funded internally by Guy's Hospital. Contact details: **Hannah.Maple@gstt.nhs.uk**

The Effects of Expressive Writing on Haemodialysis Patients Distress is common in dialysis patients and associated with poor outcomes. Few studies have examined the effectiveness of psychological interventions aimed at improving psychological distress in dialysis patients. Expressive Writing is a therapeutic technique that typically