Renal and Urogenital research

taking place at North Bristol NHS Trust.

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R&D No	Project Title	Project Description
2854 End date: 31/12/2020	NephroS: The National Study of Nephrotic Syndrome NURTuRE	A study to correlate the epidemiological and clinical features of Steroid Resistance Nephrotic Syndrome including FSGS (Focal Segmental GlomeruloSclerosis) in childhood, in the UK, with genotype and to develop biomarkers of disease activity post transplantation
2962 End date: 31/12/2019	RADAR	National Studies of Rare Kidney Diseases
2970 End date: 01/09/2021	The UK Calciphylaxis Study	Calciphylaxis is a rare condition which results in small arteries becoming calcified. This results in painful ulceration of the skin which in turn can result in infection and further damage to tissue. It is associated with a high mortality rate (60–80%). The aims of this study are to determine the following: 1) What is the natural history of the disease? 2) What risk factors are associated with development and progression of calciphylaxis? 3) Which treatments currently in clinical practice confer a favourable outcome? 4) What are the underlying disease processes?
3692 End date: 30/11/2020	PUrE: Surgical Interventions for Renal Stones	The clinical and cost effectiveness of surgical interventions for stones in the lower kidney: The Pure RCTPercutaneous Nephrolithotomy (PNL), Flexible Ureterorenoscopy (FURS) and Extracorporeal Lithotripsy (ESWL) for lower pole Kidney stones. Renal tract stone disease is very common and mainly affects adults of working age and the incidence has been increasing. Approximately 50% of renal stones will cause symptoms and up to 26% will require an active intervention. Currently the NHS has three treatment options for lower pole kidney stones, extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PNL) and flexible ureterorenoscopy with laser lithotripsy (FURS). This UK wide multi-centre RCT (with internal feasibility) will determine for lower pole stones whether flexible ureterorenoscopy with laser lithotripsy result in better quality of life (EQ-5D) than ESWL or PNL (chosen according

		to stone size).
3724 End date: 31/12/2019	UKIVAS	Primary systemic vasculitidies (PSV), encompassing Anti-Neutrophil Cytoplasmic Antibody (ANCA) associated vasculitis and medium vessel vasculitis, are relatively uncommon diseases, but have a propensity for renal involvement and account for a significant number of patients with both acute and chronic kidney disease. The aetiology of PSV is unknown and current therapies are non-specific and associated with major side effects. We propose to establish the first pan-UK PSV dataset, which will collect regular returns regarding patient recruitment and outcome from all participating centres. This will facilitate investigation of disease associations, outcomes and demographic trends for the UK PSV population. We will test the hypothesis that disease incidence is increasing in Indo-Asians and why the outcome may be different among different ethnic groups, as well as investigating contemporary outcomes with modern immunosuppressive protocols. In addition, we will combine clinical phenotype with genetic studies. Specifically we will investigate genetic variation between ethnic groups by looking at variations in DNA sequences that can help to explain differences in disease susceptibility. These are investigated using many DNA specific markers, called single-nucleotide polymorphisms (SNPs) whose expression will be compared between patients from different ethnic groups. Finally, we will be able to record the outcome of all patients treated with novel therapeutics, thus eliminating the significant reporting bias that exists. This will allow individual investigators to carry out particular projects mining the dataset.
3858a end date: 31/06/2019	Prepare for Kidney Care	There is evidence that some older people with many medical problems (co-morbidities) do just as well with conservative care as dialysis, but more evidence is needed to help patients and their families make the best decision. The PrepareME Trial aims to provide far better evidence to help patients and their families reach the best decision for them and influence NHS policy on care for this group of patients
3859 End date: 30/02/2019	H4RT The High-volume Haemodiafiltration vs High-flux Haemodialysis Registry Trial	We aim to establish the effectiveness and cost-effectiveness of high-volume HDF compared with high-flux HD in adult patients with ESKD on maintenance thrice weekly in-centre HD. Please visit the H4RT website for more information. https://www.bristol.ac.uk/population-health-sciences/projects/h4rt-trial/
3874 End date: 30/06/2019	BioImpedance Spectroscopy to Maintain Renal Output: The	This research aims to test whether taking regular measurements with a bio impedance device, which gives information about body composition, improves outcomes for people who have newly started haemodialysis treatment for kidney failure. In particular, the study

	BISTRO Trial	aims to see if this helps patients maintain their remaining kidney function, as this is associated with improved survival, fewer symptoms of kidney failure, fewer side effects of dialysis treatment and a better quality of life including confidence in managing their health, and cost benefit analysis.
3963 End date: 24/09/2019	ITOPS	Improving Transplant Opportunities for Patients who are Sensitised (ITOPS) – a feasibility, randomised, controlled phase III trial Antibodies against non-self-tissue types may result from previous pregnancy, blood transfusion or transplantation. An individual in whom tissue type antibodies are detected is considered "sensitised". At the time of transplant, if an antibody is present that is directed against the new kidney, it can recognise the kidney and cause immediate rejection. Highly sensitised patients are those who have antibodies directed against more than 85% of their potential donors, and are difficult to transplant. Due to the risk of immediate rejection, they may not be able to receive a kidney directly from their living donor, and may wait a long time for the offer of a deceased donor transplant. This study will determine the effectiveness of a treatment regimen to reduce the antibodies causing sensitisation. The study will include two groups of patients, one of which will receive treatment to reduce sensitisation, and a second control group which will receive no intervention. The control group will have their antibodies measured every three months, as is the case for routine monitoring. All patients in both groups will remain eligible throughout the study for any compatible transplants that are offered. The treatment includes a technique to remove antibodies plasmapheresis) together with a combination of drugs to prevent their re-synthesis (rituximab, dexamethasone and ortezomib). Rituximab is given first. After three weeks, plasmapheresis followed by bortezomib and dexamethasone is given twice weekly on four occasions. In this treatment group, the change in antibodies is measured after 1, 2, 4, 8 and 12 weeks, then every 4 weeks to one year. If there is only a small reduction in the level of sensitisation, a second course of treatment will be carried out after three months. The fall in antibody levels is predicted to increase the chance of a transplant offer being received from either a deceased donor or through the National Living Donor Kidney Sharing Schemes (NLDKSS)
4021 End date: 30/10/2023	Cholecalciferol in Patients on Dialysis – SIMPLIFIED	Survival Improvement with Cholecalciferol in Patients on Dialysis – The SIMPLIFIED Registry Trial Vitamin D deficiency is common in kidney failure, and is a strong predictor of death from cardiovascular disease, infections and cancer. Dialysis patients typically receive pre-activated vitamin D, since it used

		to be thought that only the kidneys activate vitamin D. However, this increases blood calcium concentrations and may paradoxically make vitamin D deficiency worse. International treatment guidelines now recommend that kidney patients receive inactive vitamin D (known as cholecalciferol), since we now know that every organ activates vitamin D as required, even in kidney failure. However, this approach has not yet been tested in a trial. We will test whether supplementation with cholecalciferol increases survival in UK dialysis patients. We will randomly assign adult UK dialysis patients to cholecalciferol or standard care. We will determine the number of deaths over time in the two groups, to establish whether cholecalciferol improves survival. Whether patients are alive or dead at the end of the study will be determined from the national deaths register. We will also measure any differences in survival free from cardiovascular events, infections and cancers, the three leading causes of death in those on dialysis. We will use questionnaires to compare the quality of life of those in the two groups. This trial is designed to detect whether cholecalciferol has a clinically relevant effect by saving 4 or more lives for every 100 patients treated.
4042 End date: 01/06/2023	PASS for Patients Prescribed JINARC® for Autosomal Dominant Polycystic Kidney Disease	A 6-year, Multicentre, Non-interventional, Post-authorisation Safety Study for Patients Prescribed JINARC® for Autosomal Dominant Polycystic Kidney Disease
4078 End date: 31/08/2021	RENA 4590 (ASCEND-ND)	A phase 3 randomized, open-label (sponsor-blind), active-controlled, parallel-group, multi-centre, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa
4119 End date: 01/02/2020	PITHIA	Pre-Implantation Trial of Histopathology In renal Allografts There is a great shortage of kidneys for transplantation. All kidneys from deceased donors carry risk to the recipient (risk of not working, or of disease transmission), but donor age is strongly associated with poor function and early failure of the kidney transplant. This is important, because the majority of the pool of potential UK deceased donors are now over 60 years old. Thus, if we can improve our identification of kidneys from older donors that are better ‘quality’, we can maximise numbers of transplants performed without compromising transplant outcomes.

		The use of urgent kidney biopsy (analysis of a small portion under the microscope) to identify age-related damage has been reported to aid selection of those kidneys from older donors that are good enough 'quality' for transplantation. This approach has not been widely adopted in the UK, because the exact impact that the extra information provided by biopsy has on transplant numbers and on transplant outcomes is not clear, and its cost effectiveness remains unproven. Our study will evaluate whether providing an urgent 24 hour National Biopsy Service increases the number and function of kidneys transplanted from donors aged over 60 years. The study is a national trial: every four months a randomly-chosen group of UK kidney transplant centres will be offered access to the National Biopsy Service (a 'stepped-wedge cluster randomised trial'). By the end of the trial, all UK centres will have access, and we will then compare results for each centre from before and after the biopsy service was made available as well as evaluating the cost of providing the service. We anticipate that this comparison will show that biopsy availability increases the use of kidneys from elderly donors by about 10%, which equates to an additional 180 kidney transplants performed in the UK per year.
4154 End date: 18/02/2021	NEFECON in patients with primary IGA-Nephropathy Caliditas	A randomized, double-blind, placebo controlled study to evaluate efficacy and safety of NEFECON in patients with Primary IGA Nephropathy at risk of progressing to end-stage renal disease (NeflgArd)
4212 End date: 30/11/2019	The EMPA-KIDNEY Study	A multicentre international randomized parallel group double-blind placebo-controlled clinical trial of EMPAgliflozin once daily to assess cardio-renal outcomes in patients with chronic kidney disease.
4348 End date: 12/08/2019	The UNPACK Study: Phase 1	Understanding treatment preferences of older Patients and their families deciding between dialysis and comprehensive conservative care for Kidney failure (Phase 1). Individuals approaching kidney failure must choose between transplantation, dialysis, and non-dialysis care (also known as 'comprehensive conservative care' - CCC). Older people are rarely medically suitable for transplantation and are more likely to choose CCC than younger people. This may be because they don't want intrusive treatment and are willing to live shorter lives to avoid it. Dialysis is particularly burdensome for them, with marginal survival benefit. Family members are also involved in decision-making, but may be less willing to consider reduced survival to reduce treatment burden. The trade-offs that older UK patients and their family

		members are prepared to make have never been quantified. The UNPACK study will characterise and compare preferences of older patients and their family members deciding between dialysis or CCC. It will develop a discrete choice experiment where hypothetical scenarios are used to elicit, quantify and rank treatment preferences.
4362 End date: 31/10/2019	SONAR Study	Surveillance of arteriovenous fistulae using ultrasound (SONAR) v1.0 The kidneys are required for excretion of excess fluid and harmful toxins. If a person develops kidney failure, the build-up of toxins and fluid can be fatal within a few days if untreated. Consequently, patients with kidney failure require either a replacement kidney (kidney transplant) or for the excess fluid and toxins to be removed from the body (dialysis). The commonest form of dialysis involves blood being filtered by a machine to remove toxins and excessive fluid (haemodialysis). This requires a brisk flow of blood through the machine to allow the toxins to be removed. The safest way to achieve sufficient flow in the machine is by a small operation that involves joining one of the veins to one of the arteries in the arm (an arteriovenous fistula). With time, this fistula increases in size and allows sufficient flow through it to enable dialysis nurses to put two needles into the fistula (one taking blood from patient to machine, and the other returning the "cleansed" blood to the patient). Unfortunately, the creation of an arteriovenous fistula is not an exact science and up to half of them fail within a year of being created. The reasons why this happens and how we can prevent it are largely unknown. Our study will examine whether we can use 'Doppler ultrasound' to identify early problems with a fistula that may lead to it failing. At present we do not know if it is possible to identify problems in this way, or when it is best to perform a scan. If we were able to identify fistulas that may fail, then we would aim to perform a second study to see whether it is possible to intervene at an early stage in those "at risk" fistulas to prevent them from failing.