Diabetes Research

taking place at North Bristol NHS Trust

To discover more clinical trials that are taking place, visit the UK Clinical Trials Gateway. You can search by a particular health condition, trial or drug name.

R&I No	Project Title	Project Description
1322 End date: 01/09/2019	DRN100 (TrialNet)	TrialNet Natural History Study of the Development of Type 1 Diabetes. Phase 1, 2 and 3.
3190 End date: 31/12/2020	NN304-4016 Diabetes Pregnancy Registry	An international non-interventional prospective cohort study to evaluate the safety of treatment with Levemir (insulin detemir) in pregnant women with diabetes mellitus
3318 End date: 31/03/2019	DRN 850 TrialNet LIFT Study	Long Term investigative Follow-up in TrialNet (LIFT) The aim of this study is to provide long term follow up information on people who have previously taken part in a TrialNet study. Participants will be invited to join this study at the end of an intervention trial or when they are diagnosed with diabetes in either the TrialNet Natural History study or another TrialNet intervention study. The long term effects of receiving an intervention or of being diagnosed with diabetes at an early point in the disease process will be studied. This will help fill the gaps in knowledge about what changes occur around the time of diagnosis of type 1 diabetes and beyond, and the impact of pre-diabetes values to post diagnosis clinical course. Study visits will be either annual or semi-annual and will involve a Mixed Meal tolerance test or an oral glucose tolerance test depending on participant c-peptide and diabetes status on entry to the study. As the study is designed to give long term follow up information an end date has not been set and participants can stay in follow up as long as LIFT continues.
3361 End date: 01/04/2022	FADES (Feeding and Autoimmunity in Down's syndrome Evaluation Study)	Children with Down's Syndrome (DS) have increased risk of autoimmune conditions where the body's immune system attacks its own cells, such as thyroid problems, diabetes and coeliac disease (causing problems absorbing food). In DS autoimmunity is likely to be related to inherent defects in the immune system. The increased risk of diabetes related autoimmunity is despite a reduced prevalence of the usual genes that are seen in people who develop diabetes. Infant feeding practice has been linked to diabetes and coeliac risk with some evidence that prolonged

		breastfeeding is protective. We hypothesise that in infants with DS, already at increased risk, early feeding practices may be related to the development of autoimmunity. Children with DS may have difficulties with breastfeeding leading to rapid introduction of formula feeds.
3371 End date: 14/06/2019	Unravelling mechanisms of stem cell depletion in diabetes	Unravelling mechanisms of stem cell depletion for preservation of regenerative fitness in patients with diabetes. Study limited to working with human tissue samples (or other human biological samples) and data (specific project only).
3456 End date: 01/09/2019	TrialNet-TN18 Abatacept Prevention	The TrialNet Type 1 Diabetes Protocol TN-18, CTLA-4 Ig (Abatacept) for Prevention of Abnormal Glucose Tolerance and Diabetes in Relatives At-Risk for Type 1 Diabetes Mellitus, describes the background, design, and organization of the study. The protocol will be maintained by the TrialNet Coordinating Center (TNCC) over the course of the study through new releases of the entire protocol, or issuance of updates either in the form of revisions of complete chapters or pages thereof, or in the form of supplemental protocol memoranda.
3748 End date: 31/08/2020	Dynamic Hormone Diagnostics (ULTRADIAN)	Hormones are released from organs under a specific rhythm creating a typical hormonal pattern. That rhythmicity may be either longer than 24 hours, shorter or appear in hourly intervals. This rhythm is essential for maintenance of proper body function, composition and reaction to different stimuli. Disordered rhythmicity of hormones is seen in several diseases; consequently treatment of endocrine diseases should respect hormonal rhythms. Unfortunately, current diagnostic protocols rely on a single blood test being taken mostly in the morning and treatment modalities fail to respect these rhythms, together this can lead to misinterpretation of results, delay in diagnosis and repetitive admission of patient to the hospital. Moreover, unphysiological treatment increases number of long term complications and shortens life expectancy. We would like to introduce a new tool that in the future could be used for the diagnosis and monitoring of endocrine disorders. That tool- ULTRADIAN consist of a pump and collector which has been already successfully used in human research. The microdialysis technique enables us to measure hormones for 24 hours in tissues that surrounds cells. It is comfortable for the patients, portable and can be performed at home. In the first stage we will determine normal curves/patterns of hormones in healthy volunteers and then compare these patterns to patients with endocrine disorders. This study is proof of concept

		that 24 hour hormonal survey will detect meaningful differences/changes in hormonal patterns of secretion which in the future could be utilised to allow earlier diagnosis and serve as a tool for monitoring and individualizing treatment.
3845 End date: 30/04/2021	StartRight (Main Study)	To assess whether blood tests, either alone or in combination with clinical features, can help us tell if a patient needs rapid insulin treatment and should be initially treated as Type 1 or Type 2 diabetes. The treatment of Type 1 and Type 2 diabetes is very different. People with Type 1 diabetes rapidly stop making their own insulin, so need insulin injections from diagnosis. People with Type 2 diabetes can keep making their own insulin but it may not work as well as it should, so they can be treated with diet or tablets. While they may eventually need insulin treatment it is usually not until many years after diagnosis. It is often difficult for doctors to tell which kind of diabetes a person has, particularly in younger adults where both Type 1 and Type 2 diabetes are common. Because of this, sometimes (in about 15-20% of young adults) people are given the wrong diagnosis. This can have a huge impact as it means they could receive the wrong treatment. A person incorrectly diagnosed with Type 1 diabetes will be prescribed unnecessary insulin injections and miss out on other helpful therapies. A person incorrectly diagnosed with Type 2 diabetes may develop severely high glucose and become unwell with a condition called Diabetic Ketoacidosis if they do not receive insulin treatment.
3839 End date: 31/01/2020	TriMaster v1	Randomised Double-Blind Crossover study of a DPP4 inhibitor, SGLT2 inhibitor and thiazolidinedione as third line therapy in patients with type 2 diabetes who have suboptimal glycaemic control on dual therapy with metformin and a sulphonylurea. The TriMaster trial is part of the larger MASTERMIND project which aims to help identify the most suitable treatment for patients with type 2 diabetes. It is known that patients with type 2 diabetes vary greatly in how well they respond to different diabetes drugs and whether they develop side effects to particular medications. In this study the research team aims to identify subgroups of patients that respond well or poorly to third-line therapies based on particular clinical characteristics such as their BMI and renal function. The current choice for non-injectable third-line therapy is between a DPP4 inhibitor, an SGLT2 inhibitor and a thiazolidinedione (TZD). However the decision of which treatment to choose lacks guidance on which patients will respond well or poorly to a particular therapy. This study is a randomised double-blind crossover trial in patients

		with type 2 diabetes who have poor glucose control on two classes of drugs. Patients who meet the current NICE guidelines for the addition of a third-line drug will be invited to take the 3 different available therapies for 4.5 months each in random order. As these drugs work in different ways the research team will be able to test whether the different clinical characteristics affect whether they respond well to the drugs, and/or make them more likely to experience side effects.
4112 End date: 27/01/2021	Sotagliflozin in Patients with T2DM post worsening Heart Failure	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicentre Study to Evaluate the Effects of Sotagliflozin on Clinical Outcomes in HemodynamIcally Stable Patients with Type 2 Diabetes post Worsening Heart Failure(WHF) The primary objective of this study is to demonstrate that sotagliflozin reduces cardiovascular (CV) mortality and morbidity (composite of CV death or Heart Failure [HF] requiring hospitalization) compared to placebo in hemodynamically stable patients with type 2 diabetes mellitus (T2D) after hospital admission for worsening heart failure (WHF).
4234 End date: 29/03/2019	RENA 3971	A randomized, double-blind, placebo-controlled, parallel-group, multicentre, event-driven phase 3 study to investigate the efficacy of finerenone on the reduction of cardiovascular morbidity and mortality in patients with type 2 diabetes mellitus and the clinical diagnosis of early diabetic kidney disease in addition to standard of care.
4266 End date: 28/04/2020	STEP 1	Semaglutide Treatment Effect in People with obesity. Effect and safety of semaglutide 2.4 mg once-weekly in subjects with overweight or obesity.