Vascular Research

taking place at North Bristol NHS Trust.

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R&D No	Project Title	Project description
2712 End date: 31/03/2022	The European Carotid Surgery Trial-2 (ECST-2)	Comparing the risks and benefits of two treatments for carotid artery narrowing.
3668 End date 01/02/2021	BASIL-3	Multi-centre randomised controlled trial of clinical and cost-effectiveness of drug coated balloons, drug eluting stents and plain balloon angioplasty with bail-out bare metal stent revascularisation strategies for severe limb ischaemia due to atherosclerotic femoro-popliteal, with or without infra-popliteal involvement, peripheral arterial disease. Endovascular treatment, involves opening up blocked arteries using balloons (a procedure called angioplasty) and little metal tubes (called stents). These endovascular procedures are well established methods of treating severe limb ischaemia. They have been used previously for many years in many hundreds of thousands of patients around the world. However, nobody knows whether using balloons coated in a drug that is meant to help keeping the artery from blocking again is actually any better than using a plain uncoated balloon, or whether using a stent that slowly releases drugs is better than a simple bare metal stent. The principal reserach objective for BASIL-3 is to determine which of these methods (plain balloon, drug-coated balloon or drug releasing stent) keeps the patient alive and with their leg intact, the longest. This is called amputation free survival.The trial will look at the first attempt to keep the artery open and if this first attempt fails then the doctor will use whichever method they feel is most beneficial to the patient, in the circumstances.
3529 End date: 31/12/19	BASIL -2	Study looks at vein bypass first versus best endovascular first, in terms of clinical and cost effectiveness for severe limb ischaemia due to infra-popliteal disease.
3903 End date:	Pluristem	A randomised double blind placebo controlled study to look at the efficacy, tolerability and safety of intramuscular injections

29/02/2019		using stem cells for the treatment of patients' with critical limb ischaemia with minor tissue loss who are unsuitable for revascularisation
4003 End date: 31/05/2022	SAVER	The purpose of SAVER is to collect data on the patients treated with a drug-coated angioplasty balloon called Stellarex™ and assess the balloon's performance.
4056 End date: 31/07/2019	NESIC Version 1.0	Does Neuromuscular Electrical Stimulation Improve the Absolute Walking Distance in Patients with Intermittent Claudication (NESIC) compared to best available treatment? A Multicentre Randomised Controlled Study. This is a vascular randomised controlled study that will assess the benefit of using a neuromuscular electrical stimulation (NMES) device as an adjunct to the local standard care that is available at the study sites, compared to local standard care alone. The device is expected to increase the walking distance in patients with intermittent claudication (IC), and therefore have an adjuvant benefit on the same when provided in addition to supervised exercise programmes. It is also expected to cause a reduction in pain symptoms and reduced likelihood of major intervention in late stage peripheral arterial disease (PAD).
4353 End date: 01/11/19	UK-Compass	UK-COMPASS is a NIHR-HTA funded project aiming to evaluate the clinical and cost-effectiveness of strategies for the management of juxtarenal abdominal aortic aneurysm. Abdominal aortic aneurysm (AAA) is a common condition where aorta, the biggest artery, begins to bulge abnormally. Usually this expands over years and can eventually burst, causing fatal internal bleeding. When an emergency life-saving operation is possible, they have high failure rate. A planned AAA repair operation prevents a burst aneurysm. We intend to analyse the outcomes of all patients undergoing juxtarenal aneurysm treatment in England without altering their treatment, during a period of 2 years and collect 5 year follow-up. We plan to examine the routinely performed scans and utilise data that is routinely collected by the NHS. Available data will be analysed to compare the safety and effectiveness of different treatments, and to see if a particular treatment is better suited for particular features so patients can be offered bespoke treatment strategies.
4263 End date: 30/04/2020	Selfi Wound Study	Exploring the feasibility of a method for the collection of self/carer-taken images of primary surgical wounds after leaving hospital for remote and improved assessment of surgical site infection. The aim of this study is to see if it is possible for people to take

		a clear photograph of their wound after they have left hospital using their own mobile devices with cameras (e.g. smartphone, tablet computer). We want to know if this could be a useful method to use in everyday care and research studies, to help assess how the wound is healing after people have left hospital.
4350 End date: 31/03/2022	Exploring patient views of developing surgery	The development of surgical techniques and devices is usually considered an essential part of surgery, and contributes significantly to human health and wellbeing. Surgeons have significant autonomy in what, how and on whom they choose to develop surgery. Developing surgery faces less scrutiny than innovation in pharmacology. Because of this, little is known about how decisions are made to develop surgery, how the risks and benefits of using un-trialled techniques and devices is managed and the degree of patient involvement in these decisions. Better understanding of these processes forms part of the objectives of the University Hospitals Bristol NIHR Bristol BRC workstream "Improving the safe and transparent translation of surgical innovation", led by Professor Jane Blazeby. The overall aim of this theme is to shed light on three work important areas: (i) How should early phase study in surgery be designed? What is the appropriate timing for randomised evaluation? (ii) What is the role of information provision and informed consent for new and evolving surgeries? (iii) How do should we assess benefit and harm outcomes of early phase studies.