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Orthopaedics research

taking place at North Bristol NHS Trust.

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R&I No	Project Title	Project Description
3374 End date: 31/05/2020	WHiTE Study	World Hip Trauma Evaluation: A Comprehensive Cohort Study of Patients with Fracture of the Proximal Femur. Hip fractures are one of the commonest osteoporotic fracture in the UK. They are the single greatest healthcare burden in this country. They cause considerable ill-health and death for very many people. As a consequence of the importance of this injury the NHS has set up the National Hip Fracture Database to help determine how well the NHS treats patients with a hip fracture and to try to improve this service. This study aims to record important additional patient-centred outcomes of treatment. Using this information we aim to be able to test new treatments that may in the future improve our treatment of patients with a hip fracture.
3694 End date: 30/04/2019	WHiTE Four	The aim of this trial is to investigate the patients' quality of life after a Xbolt dynamic plating system compared with the sliding hip screw in the treatment of trochanteric fractures of the hip.
3650 End date: 01/11/2022	SMR STEMLESS	A multicentre, prospective clinical study analysing outcomes of shoulder arthroplasty with SMR STEMLESS The SMR STEMLESS clinical study is a research project following patients treated with a novel design of shoulder replacement. It will include patients suffering from severe joint diseases of the shoulder and who require shoulder replacement surgery. Shoulder replacement surgery is aimed at relieving pain and restoring shoulder function. Current shoulder replacements frequently involve insertion of a "stem" into the upper arm bone (humerus). This can lead to complications thought to be due to the "stem". (may wish to include some brief complications here). The stemless replacement (SMR STEMLESS) has been designed with the aim of reducing these complications. The objective of this study is therefore to explore how well people recover after shoulder replacement with this novel stemless shoulder replacement. This will be assessed over 5 years in three different countries in Europe using patient completed questionnaires and clinical and X-ray assessments
3675 End date: 30/08/2019	STAR Work Package 5: IMPARt	This study focuses on living with long-term pain after knee replacement. We aim to develop guidance for patients and health professionals about how best to engage people with long-term post-surgical pain with healthcare services. We will interview up to 40 patients with long-term

		pain after total knee replacement who have made little or no use of formal healthcare services for ongoing pain. During the interviews we will explore topics such as experience of pain after surgery, pain in relation to other illness conditions, how pain affects their life, and the decisions they make about using healthcare services.
3759 End date: 31/05/2020	The STAR trial	Evaluation of a care pathway for patients with long-term pain after knee replacement. Our proposed study will run a trial of a new, best care pathway to see if it is of benefit to patients with long-term pain after knee replacement. We will recruit 380 patients with pain at 3 months after knee replacement from four hospitals in the UK. Two-thirds of patients will be randomly chosen to receive the STAR care pathway and one-third of patients will receive the usual care that their hospital provides. The STAR pathway involves a clinic appointment with a healthcare professional to better understand the possible causes of pain after knee replacement. People will then be referred to see relevant health professionals for treatment as needed, such as physiotherapists, orthopaedic surgeons, GPs, or pain specialists. We may decide that for some people the most appropriate course of action is to regularly monitor their pain, and then begin treatment if the pain worsens. We will ask everyone in the study to complete questionnaires after 6 months and 12 months to see if the STAR care pathway improves patients' pain. We will also collect information to compare the cost of providing both treatments. The findings from this study will help us to know if providing the STAR care pathway can improve patients' outcomes after knee replacement and is good value for money to invest NHS resources.
3891 End date: 01/11/2019	DRAFFT 2	Distal Radius Acute Fracture Fixation Trial - A Randomised Controlled Trial of Manipulation and surgical fixation with K-wires versus Manipulation and Casting in the Treatment of Adult Patients with a Dorsally Displaced Fracture of the Distal Radius
4068 End date: 31/12/2021	AIR: Ankle Injury Rehab	A multi-centre randomised controlled trial to assess the difference between plaster cast and functional bracing in the management of ankle fractures. All adults with a fractured ankle under the care of a clinician at any of the named recruiting sites are potentially eligible. New patients with an ankle fracture are reviewed each day by the trauma team and will be randomised to receive either a cast or a functional brace/fixed angle removable orthotic (FARO).
4115 End date: 31/12/2020	TULIP	A Randomised Controlled Trial of Surgical versus Non-Surgical Treatment of Lateral Compression Injuries of the Pelvis with Complete Sacral Fractures (LC1) in the Non-fragility Fracture Patient - A Feasibility Study.
4163 End date:	AceFIT	Acetabular Fractures in older patients Intervention Trial. A feasibility study comparing three methods of treatment of acetabular fractures in

30/09/2019		older patients; surgical fixation versus surgical fixation and hip replacement versus non-surgical treatment. Currently we do not know which of these treatments is best. We are proposing to undertake a randomised study comparing theses three treatments; non-surgical treatment, surgical fixation and surgical fixation combined with hip replacement in older patients. Patients who are eligible and have agreed to participate will be randomly allocated to one of the three treatment groups; 20 patients will not receive any surgery and will be encouraged to weight bear as tolerated, 20 patients will receive surgical fixation and 20 surgical fixation combined with hip replacement. We will collect information from patients (and their carers) about their health before they receive their allocated treatment and collect more information (including complications, health related questionnaires, length of stay and x-ray pictures) at 6 weeks, 6 months and 9 months after their surgery. This will allow us to assess the feasibility of comparing the treatments at the end of a subsequent more definitive study.
4202 End date: 31/05/2021	PROFHER-2	Breaking (fracturing) the upper part of the arm at the shoulder (proximal humerus) most commonly occurs in people over 65 years old from a simple fall. When the bone is broken into more than 2 parts (typically 3 or 4 parts), patients may undergo surgery to replace the broken bone with an artificial shoulder joint. There are two main types of joint replacement used: hemiarthroplasty (replacing the broken ball of the joint) and reverse shoulder arthroplasty (replaces the ball with a socket and the socket with a ball (hence 'reverse')). Another common treatment is non-surgical care where the arm is supported in a sling to allow the broken bone to heal naturally. Following each of these treatments, physiotherapy is needed to regain arm function. We do not know which surgery leads to the best recovery and whether surgery is better than non-surgical care. PROFHER-2 will assess whether reverse shoulder arthroplasty is more effective than hemiarthroplasty at restoring use of the shoulder and arm, whether shoulder replacement surgery is more effective than non-surgical treatment for these fractures, and which treatment is best value for money. Patients aged 65 years or older, with complex fractures of the proximal humerus, will be invited to take part. Patients who agree to take part will receive one of the three treatments selected at random using a computer system. If patients need general anaesthetic to treat a dislocation they will receive one of the two types of surgery. All patients will receive physiotherapy and rehabilitation, and will have usual check-ups with their treating doctor. Questionnaires will assess how well patients can use their arm and shoulder over a two-year period and we also plan to follow-up patients after five years to assess whether they need any further surgery.

4249 End date: 31/12/2021	START: REACTS	Sub-acromial spacer for Tears Affecting Rotator cuff Tendons: a Randomised, Efficient, Adaptive Clinical Trial in Surgery. The aim of this study is to compare arthroscopic debridement (the standard operation) to arthroscopic debridement with the InSpace balloon. The study aims to recruit 212 people needing shoulder surgery from 10 expert centres, which will ensure that well-trained surgeons are performing the procedure correctly. Patients will be randomly allocated to one or other treatment. As the incisions and post-operative physiotherapy are the same, neither the patient nor the person assessing the results will know which treatment has been given. This will ensure a fair and unbiased comparison. Patients will be seen at three, six, and 12 months when we will measure strength, range of motion and pain. We will also use questionnaires to assess disability, quality of life, and costs, including lost earnings. A group of 56 patients will also have shoulder scans taken six-weeks and six-months after surgery, to assess the way the balloon is thought to work. This study will determine whether the device improves shoulder function, pain and quality of life following this shoulder operation. We will also assess the link between costs and the benefits that the treatment gives. This will improve care for patients suffering from a difficult condition to treat and it will also advance the way we assess new surgical procedures and run clinical trials in the future.
4278 End date: 15/12/2021	WHiTE 8 COPAL	A Randomised Controlled Trial of low dose single antibiotic loaded cement versus high dose dual antibiotic loaded cement in patients receiving a hip hemiarthroplasty after fracture.
4330 End date: 30/11/2021	ARTISAN	Acute Rehabilitation following Traumatic anterior shoulder dislocation. Shoulder dislocations occur when the upper end of the arm bone is forced out of its joint socket because of a traumatic event. It is common and results in pain, disability and decreased function. Currently in the UK, some hospitals offer a single session of advice and some offer a course of physiotherapy. The UK guidelines currently say a course of physiotherapy 'may be helpful'; whilst other national guidelines say advice alone is needed. We plan to perform a study across 30 UK hospitals to compare a single session of advice versus a course of physiotherapy for patients who have dislocated their shoulder. All adult patients with a dislocated shoulder managed without an operation will be screened. All participants who are eligible and consent to take part will be allocated by chance to either a single session of advice or the same session followed by a course of physiotherapy, across 30 UK hospitals, including 478 participants part. Both treatments are widely used, and clinical teams across the UK will be familiar with both. The primary aim is to compare the two treatment groups for differences in the Oxford Shoulder Instability Score six months after injury. This score

		measures function from the patients' perspective. Improvements in functional outcome and quality of life as well as complications and resource use will be collected at six weeks, three, six and 12 months after taking part in the study. The results are planned to be presented at national conferences, published in high quality journals and social media outlets. Lay team members will be supported to produce lay summaries of the research to be disseminated across the trial sites and individual trial participants.