Glenohumeral Cortisone Injection

NCT04216017

Jonah Hebert-Davies

Protocol

4/16/2018

CLEAR 2018

Aim(s)

The primary objective of this study is to determine the feasibility of performing a large scale trial to address post traumatic decreased range of motion in patients with proximal humerus fractures.

Background and Significance

Shoulder stiffness is a known complication of proximal humerus fractures with the potential for serious functional impact. Significant decrease in range of motion has been documented in up to 20-42% of patients at one year post fracture. This lack of motion has been seen in patients treated both operatively and nonoperatively. Standard of care includes physical therapy, home exercise program and watchful waiting. Decreased range of motion can be very debilitating and greatly impacts activities of daily living (ADLs) including personal hygiene and feeding.

Adhesive capsulitis is a distinct clinical disorder causing similar symptoms of pain and stiffness but is not associated with fractures. Physical therapy including a home exercise program is the mainstay of treatment however, intra-articular steroid injections have been shown to provide significant short-term benefits regarding pain, range of motion (ROM), and shoulder function compared with other nonoperative treatments. Currently it is not known whether this treatment is applicable to patients with proximal humerus fractures as the pathophysiology differs. Applying results from this patient population to patients with proximal humerus fractures could lead to increased outcomes. Early intervention may also decrease time off work and help patients obtain peak outcome at an earlier time.

Approach

The goal of this study is to determine the feasibility of a large scale multi-centered randomized trial to evaluate the usefulness of this technique. The pilot study will take place in a single center. We will recruit patients with both operative and non-operative proximal humerus fractures during routine follow-up. Patients will be screened at 6 weeks after fracture treatment for the presence of decreased range of motion (defined as a loss of passive motion > 30° in 2 or more planes of movement). Those patients would then be randomized to receive standard of care (including physical therapy) or an ultrasound guided intraarticular cortisone injection in addition to standard of care. All research

participants will follow the same rehabilitation protocol included referral to physical therapy and a home exercise program. The time of inclusion in the study will be considered time zero. Clinical evaluation and validated functional outcomes will be completed initially (which will be considered “baseline”) and at follow-up after 6, 12 and 24 weeks. Physical examination will document both passive and active range of motion (ROM) in standardized fashion. The primary outcome measure will be American shoulder and elbow society(ASES) score. This validated functional score is used for a multitude of shoulder pathologies including fractures, arthroplasty and rotator cuff disease. Secondary outcomes will be the visual analog score(VAS), passive ROM, return to work/activity and the abbreviated Constant-Murley score. The VAS was chosen because pain is often a significant component of post-operative stiffness and outpatient narcotics is a notoriously unreliable metric. Return to work or activity was chosen because there is a potential for decreased study effect over time. However, even if range of motion is not significantly different at one year, and earlier return to work would be considered a positive outcome. Considering the scope and goal of this trial and using a known MCID for the ASES score (primary outcome), a sample size of 20 patients in each group will be sufficient for this pilot study.

The most significant portion of the study cost will be paying for the study intervention (cortisone injection). We believe that standard of care for these fractures includes physical therapy and home exercise program but does not include an intraarticular injection. Therefore, in order to limit any potential harm to patients enrolled in the study, we have opted to pay any out of pocket expenses for the intervention. We have negotiated a fee reduction (52.3%) with the radiology department which represents approximately 680$ per patient. The other significant cost will be the hiring of a temporary research assistant who will help recruit patients and document functional outcome scores. This person will be present 3 days per week during orthopedic trauma clinics. Based on fracture incidence at our institution, we believe that recruitment should be reached in 6-8 months. We have therefore budgeted for 12 months to account for missed recruitment/seasonal variability. All budget requirements above the funds provided in this grant will be paid for by a matched departmental research fund. IRB approval will be obtained prior to the grant period start. If any significant changes are required by the IRB committee, these will be communicated to the CLEAR funding directors.

With expected results 18-24 months after the study start date, we hope to move to a multicentered study within 36 months. We have already identified 3 other potential sites and will be ready to start relatively quickly after. Once the pilot study has begun and we have preliminary data showing the efficacy of the protocol, we will begin applying for funding for the full trial.