RESEARCH PROTOCOL

A RANDOMISED CONTROLLED TRIAL TO DETERMINE WHETHER INJECTION PRIOR TO PHYSIOTHERAPY IMPROVES THE OUTCOME FOR MASSIVE ROTATOR CUFF TEARS AND WHICH MUSCLES ARE USED TO REPLACE THE ROTATOR CUFF IN PATIENTS WITH GOOD FUNCTION AND KNOWN MASSIVE CUFF TEAR

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Objective of the study

1. To identify the effect of injection prior to physiotherapy in patients with rotator cuff (RC) tears
2. To determine the activation pattern of other muscles following physiotherapy that replace the RC to achieve the shoulder function.
3. To find out whether the size and location of the RC tear affects rehabilitation.

Abstract

Research need: There is a scientific limitation observed in the literature with regard to the improved physiotherapy outcome for patients with RC tears. It may be due to pain limiting compliance with physiotherapy exercise programmes. Therefore, it may be useful to find out whether administration of a steroid injection one week prior to commencement of physiotherapy would improve the outcome. In addition, it may be beneficial to know the activation pattern of the other muscles that assist in achieving shoulder function during RC injury. It may also be useful to find out whether size and location of the RC tears in the shoulder affects the physiotherapy rehabilitation process. Steroids are a commonly used drug that are given locally to painful areas for pain relief.

Related Research: Ainsworth (2006) demonstrated the outcomes for pain relief and function in patients with rotator cuff tears, using an exercise program to strengthen the anterior deltoid muscle. In a later study Ainsworth

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et al., (2009), tested the physiotherapy regime using steroid injection for two groups and found that the one group improved better than the other group in terms of duration 3 to 6 month. Even though these studies demonstrated good outcomes, there was a dichotomous response in the improvement with a small population and duration of effect. The present study will identify the effect of injection 1 week prior to physiotherapy and will determine the activation pattern of other muscles in shoulder function following physiotherapy. In addition, it will also find out whether rehabilitation process is affected by the size and location of the massive RC tear.

Research Methodology: This is an observational study with randomized controlled trial (RCT). In the RCT, injection of local anaesthetic alone and a combination of local anaesthetic and steroid will be used. The activation pattern of muscles will be identified using electromyography (EMG) in the observational study. The Oxford score, Visual analogue score (VAS) and Constant scores are considered as outcome measures. Pre and post scores and EMGs data will be analysed.

Timescale: The aim is to recruit 70 patients over a 3 year period.

Introduction

The rotator cuff acts as a dynamic stabilizer of the glenohumeral joint, supporting the joint capsule (Keating JF et al1993). Pathology of the rotator cuff is considered to be one the most common causes of pain and functional restriction in the shoulder (Uhthloff HK et al1990). The incidence of rotator cuff tears increases with age (Milgrom C et al 1995). Treatment for rotator cuff tears ranges from conservative treatment (including exercise therapy and injection therapy) to surgery (Ainsworth and Lewis 2009). Rotator cuff surgery is thought to be less successful in an elderly population, and when the tendon is retracted past the glenoid rim (Gerber C et al 2000).
The larger the tear, the more retraction will occur. Kim et al (2010) defines a large rotator cuff tear as 3-5 cm, with a massive tear being greater than 5 cm. Ainsworth et al (2007) performed a systematic review of the literature for non operative management for rotator cuff repairs. No randomized controlled trials for exercise management of large – massive rotator cuff tears were found, with only 4 observational trials. Outcomes are variable in these studies, with some achieving excellent function and pain relief, whilst others do not improve. This presents a need for further research in this area.

Ainsworth (2006) demonstrated good outcomes for pain relief and function in patients with massive rotator cuff tears, using an exercise program to strengthen the anterior deltoid muscle. Rockwood et al (1995) identified that the anterior deltoid function was a good determinant of recovery following decompression surgery for massive, irreparable cuff tears. Ainsworth (2006) suggests that the patient who achieves good function utilizes the anterior portion of the deltoid in order to achieve elevation without upward shearing of

the humeral head. However this was a small scale, observational pilot study of only 10 patients. This does not give a large enough population to identify which patients do well and which do not achieve good results. However, when looking in to Ainsworth's results in depth, it can be seen that there was a dichotomous response, with 6 showing a marked significant improvement on the Oxford score, whilst 4 showed minimal change. This approximately 60% response rate has been observed clinically in the physiotherapy department in UHL.

In a later study (Ainsworth and lewis 2009) where this physiotherapy regime was tested in a randomized controlled trial against placebo, they gave steroid injections for pain relief as needed to both groups and found that both groups improved but those undertaking the Ainsworth regime gave better range of movement than the placebo at 3 and 6 months but not a year. We hypothesise that it may be pain that limits those who are unable to comply with the physiotherapy regime, therefore by injecting patients with local anesthetic and steroid 1 week prior to commencing physiotherapy, the response rate should improve.

Steroid is a very powerful anti-inflammatory drug that is given locally to painful and inflamed areas in orthopaedics. It is in common use usually being combined with a local anaesthetic. It is usually given to provide initial pain relief in cases where there is an area that is inflamed. So for example it may be given as the treatment for a condition called impingement syndrome where the cuff is squashed but not torn. It is found that if the space above the shoulder is not too tight the condition may settle permanently. Anecdotally it has also been found that it may relieve the pain of impingement syndrome when the cuff is torn(and it is licensed for this). The mechanism by which it works is not certain however it may also work by reducing inflammation. In everyday practice steroids are given to patients with rotator cuff tears where a repair is considered inappropriate for pain relief if required.

Sometimes it has been given to help pain prior to or during physiotherapy(eg in the Ainsworth study(2009). The Cochrane review of corticosteroid injections for shoulder pathology (2003) found there may be a short term effect of pain relief in patients with rotator cuff pathology. Although Alvarez et al(2006) found that steroid was no more effective in improving the quality of life, range of motion, or impingement sign than local anesthetic alone in patients with chronic rotator cuff tendinosis. However he was only treating chronic patients and not acute tears as in our study. Therefore the timing of the injections was thought to be important to have the pain relieving effect to allow the physiotherapy exercises to be performed.

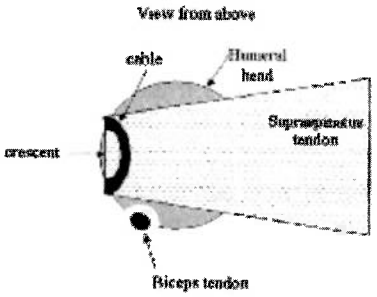
Due to waiting lists the injections performed are often several weeks before the patient receives physiotherapy and therefore the pain relieving effects directly attributed to the injection would not be working whilst the patients are undertaking physiotherapy. We therefore wished to see if injecting the patients shoulder with local anaesthetic or a combination of steroid and local

anesthetic one week prior to starting physiotherapy would assist the patients in performing exercises due to the pain relief achieved with the injection.

In addition to the review of the response to injection of steroid and local anesthetic versus local anesthetic alone, this study aims to make further observational reviews that may assist in understanding why certain patients recover well with physiotherapy and some don't. These factors include 1) the location of the tear, and 2) muscle activation patterns.

Location of the tear

This study aims to try and formulate a hypothesis as to why some do well by looking in to the location of the tear. Burkhart (1992) suggested the theory of the rotator cable. He notes that a cable of thicker, well perfused tissue connects the anterior and posterior edges of the supraspintus tendon medially. This thickened tendon 'cable' separates the musculotendinous junction from a crescent shaped area of the lateral aspect of the supraspinatus tendon, where most rotator cuff tears occur.



Ref: Shoulder, rotator cuff injury (MRI) author: Michael Tuite, Matthew Sandford, emedicine Jun2009

Although the rotator cuff "cable" is seen histologically, it is not normally identifiable on MRIs. Burkhead (1995) believes that even full-thickness tears isolated to this crescent-shaped portion of the rotator cuff can solely be debrided and that patients will do well without significant loss of rotator cuff function.

Machizuki et al (2008) found the anterior 1.5mm of the supraspinatus tendon is the strongest part and carries most of the load of the supraspinatus. Disruption at this area is thought to give the highest loss of function and power. This is a similar theory Burkhart's (1992) rotator cable theory and would indicate that the site of the tear is possibly an important indicator as to whether the patient will retain function after a rotator cuff tear.

Kim et al (2010) found tears in the most anterior part of supraspinatus are most likely to develop fatty degeneration in the supraspinatus muscles compared to tears more posterior in the tendon. They also found the larger the tear size in infraspinatus the more likely the chances of fatty degeneration of the muscle belly. Therefore we propose that the size of the tear and also

the site of the tear may be indicators as to whether the patient will achieve good function after an acute injury.

This study proposes to look at the size and position of the rotator cuff tears as diagnosed by routine clinical ultrasound and determine whether the outcomes of physiotherapy corresponds to the size and position of the tears.

Muscle Activation Patterns

In addition, we aim to review the muscle activation patterns of these patients in order to formulate a hypothesis regarding muscle patterning that may need addressing in order to improve success rates of physiotherapy. Ainsworth's theory (2006) is that it is the anterior deltoid that is recruited in patients that do well, in order to achieve elevation without the upward migration of the humeral head. However, Steenbrink et al (2006) looked at the changes in activation of the adductor muscles (lattissimus dorsi, pectoralis major and teres major). They hypothesized that in the absence of an intact rotator cuff, it was the middle deltoid that attempted to elevate the arm, but that the adductors were recruited to oppose the upward humeral head migration.

They found an increase in activity of the adductor muscles in the presence of pain and a rotator cuff tear which they hypothesized was an attempt to pull the humeral head distally to oppose the upwards pull of deltoid. However, with an increase in adductor activation, the ability to elevate is hindered due to this opposing force, whereas if the anterior deltoid can be recruited to elevate without the need for the adductors to activate, the patient should in theory gain more functional movement without the presence of pain. At present there are only theories regarding what muscles are recruited, with no EMG evidence to inform us regarding these patterns of movement. We therefore propose to perform EMG studies to see if those patients with good outcomes use different muscles to those with poorer outcomes.

<u>Methodology</u>

A randomized controlled trial will be performed to investigate the following hypothesis:

1) Injection of local anaesthetic alone or a combination of local anaesthetic and steroid improves outcome of physiotherapy for conservative management of large / massive rotator cuff tears

Observational Studies will also be performed to test if

A) patients with a good outcome have a different maximum voluntary activation of certain muscles on emg compared to those that do not. That those whose function improves have changed muscle activation patterns over the physiotherapy
B) Patients that have tears near to the long head of biceps tendon (rotator cable region) are less likely to achieve good outcomes with physiotherapy

See flow chart for further details (Appendix 1)

Recruitment
Patients are to be recruited from
i) A&E clinics
ii) acute referrals to the physiotherapy department
iii)orthopaedic shoulder consultant clinics.

These patients will be reviewed within the A&E clinic or orthopaedic clinic by a physiotherapy practitioner / orthopaedic consultant. They will then be assessed and if it is thought they have a rotator cuff tear they will be referred for a routine ultrasound scan. The assessment will enable inclusion and exclusion criteria to be assessed. The scan once reported is sent back and reviewed by Miss Armstrong, Consultant orthopedic surgeon(for physio and A and E referrals) or the referring orthopaedic consultant.

Patients who present with a large to massive cuff tears (greater than or equal to 3cm) are sent a letter of invitation about the trial with the routine letter inviting them to phone in for an appointment for physiotherapy. If they express interest in being involved in the trial, they indicate this when they phone and are contacted by the consenting physiotherapist after a few days and the trial procedure is explained.

An appointment is then arranged for the participants to ask any questions regarding the trial, and for consent to be gained if the patient is content to be enrolled. The unblinded physiotherapist has the role of consenting and opening a prepared envelope which will assign the treatment group and will then undertake open administration of injectable medication* to the patients and collect the initial baseline scores. They will not be involved in the patients' further treatment enabling the treating physiotherapists to remain blinded to the treatment group.

***Current practice within the trust enables the physiotherapist to administer injectable medications under the provision of a patient specific direction.**

Randomisation will be performed by using a sealed envelope system. The randomization will be done by someone not associated with the patient physiotherapy treatment. The programme used with be www.sealedenvelope.com and will be blocked randomization every 4 patients with stratification according to whether the anterior band of the supraspinatus

tendon is intact or not.. The randomization information will be kept in one of the lockable cabinets in the admin office in physiotherapy department stored by the person doing the randomization.

At the consent appointment the patient is assessed to ensure they fulfill all the inclusion/exclusion criteria as below:

Inclusion criteria

- Acute/ acute on chronic massive cuff tears
- Patients over 65 years of age
- Massive cuff tear confirmed by ultrasound scan
- Weakness of shoulder external rotation
- Painful shoulder
- Limited range of movement actively (<90 degrees elevation)

Exclusion Criteria

Main Study

- Patients under 65 years of age (may require surgery)
- Patients not able to exercise due to medical reasons
- Previous surgery to the shoulder
- lack of capacity to give informed consent
- Previous physiotherapy for the same condition
- Patients currently undergoing supervised physiotherapy for the same condition
- Patients with multiple joint pathologies
- Patients unable to comply with daily exercise and weekly appointments due to other commitments
- Passive stiffness
- Chronic tears with no acute increase in pain
- Needle phobia
- in another study which would conflict with this study
- intolerance to steroids
- Contradindication to bupivacaine and triamcinolone acetate
    - active infection either bacterial or viral
    - skin infection near site of injection
- contraindication to bupivacaine
    - Allergy to bupivacaine
    - Allergy to sodium hydroxide
    - Allergy to hydrochloric acid
    - Allergy to lidocaine or ropivicaine or other local anaesthetic of same class
- Contraindication to triamcinolone acetate
    - Allergy to triamcinolone acetate
    - Allergy to benzyl alcohol,polysorbate 80, carmellose sodium.

EMG Study

- Allergy to sticking plasters and alcohol wipes

The informed consent process will proceed if the patient is willing to participate. The consent form will indicate both the patients' willingness to take part in both the main and emg aspect of the study where appropriate. The first 16 participants in the study who are willing to participate will be sent for pre intervention emg assessment prior to injection and physiotherapy.

The randomization process will be by sealed envelope method. The master randomization list and envelopes (marked A or B).
The patients will receive either:

A - 9 ml of 0.5% bupivacaine
or
B - 9ml of 0.5% bupivacaine and 40mg of Kenalog (triamcinolone acetonide)

EMG method

EMG data will be obtained from surface electrodes, up to 12 Delsys Wireless Trigno sensors run from a Trigno base unit (Delsys, Boston, USA), sampling at 2000 Hz. Signals will be recorded with Delsys software and analysed off line with custom software written in Matlab (The MathWorks Inc., Natick, MA, USA). The skin will be thoroughly cleaned with alcohol wipes where the electrodes will be placed.
EMG will be recorded in each muscle during a maximal voluntary contraction (MVC) of $\leq$3 s while carrying out a task designed to isolate that muscle's action (a 'control' contraction). These tasks are standard physiotherapy tests with extra support of the limb. A one second window around the maximal RMS power, over a 50 ms epoch, of the signal will be used to determine the EMG amplitude during the MVC. This will be used to normalise the EMG from each muscle during the different tasks below.

The muscles of interest are as follows:
Serratus anterior, Lower trapezius, Rhomboids, Upper trapezius, Pectoralis major, Latissimus dorsi, Teres major,Anterior deltoid, Infraspinatus, Middle deltoid, Supraspinatus, Posterior deltoid. The intention is to acquire surface EMG from all these muscles for all participants but this may not be possible as it will be dependent muscularity of each subject.

We will follow the protocol described in Kelly et al. 2005 for functional tasks. Further recordings will be made during the performance of functional tasks. We will try four tasks, which may be modified in due course:
Lifting the arm forwards (no load).
Lifting the arm forwards, holding approx 0.5kg.
Holding a weight of approx 4kg beside the hip (arm straight and vertical)
Holding the hand behind the back

Carrying a bag/weight whilst walking.

These tasks will be carried out whilst recording EMG from up to 12 muscles simultaneously. Tasks will be repeated up to 5 times to allow averaging of EMG results to account for potentially poor signals from older participants with weakened musculature. The task EMG signal (re-calculated as RMS power, 50 ms epoch) will be expressed for each muscle during the functional tasks normalised against the control contraction values. RMS amplitudes, timing of EMG activation and de-activation, as well as some simple patterns of amplitude during each task will be assessed. Some cross-correlation of between muscle patterns can also be determined, especially if there are participants without recordings from some muscles.

Data from arms affected by a rotator cuff tear will be compared to data collected from normal arms under the same conditions, preferably with the control limb will being the contralateral side, otherwise it will be to group norms.

Physiotherapy Method

For all consenting participants an appointment for the injection is arranged one week before their physiotherapy is due to start. If they do not wish to be involved they will receive their physiotherapy appointment as planned. Outcome scores will be completed including VAS(visual analogue score), Oxford score(a functional shoulder score) and Constant score(measurement of movement and strength measured by physiotherapists) prior to commencing physiotherapy.
Patients will receive either an injection of local anesthetic (9 ml of 0.5% bupivicaine) only or a combined injection of local anesthetic and steroid (40mg Kenalog and 9 ml of 0.5% bupivicaine).

One week after their injection, patients will commence physiotherapy. This will be patient specific on timeframes but will follow the deltoid regime as outlined by Ainsworth (2006). The regime aims to re-educate the anterior deltoid to compensate for the torn rotator cuff. Patients are taught the exercises by the physiotherapists at Glenfield Hospital, and advised to perform them at home 3-5 times per day.

Phase 1 involves the patient lying supine, with only a small pillow to support the head. They are taught to bend their elbow and raise the arm to 90° (vertical) and then straighten the elbow. If the patient is unable to do this actively then they are taught to assist the movement with their other arm initially. Once in this position, they are taught to make circles, gradually in creasing in size. They are also taught to make forward and backwards movement, increasing the range they are working in. The movement must be smooth and controlled. Patients are advised to repeat for 5 minutes, or until they fatigue.

Phase 2 involves repeating phase 1 exercises with a light weight. Once they can perform these exercises easily, they are progress to phase 3.

Phase 3 involves increasing the incline up to a sitting position gradually (first without a weight and adding a weight in as able).

Phase 4 involves adding resistance to elevation using their other hand in a sitting or standing position. Biofeedback may be used at any stage to help patients either recruit their anterior deltoid, or to decrease the activity of their adductors to reduce the effort required for the exercises. Up to 6 treatments over a period of up to 6 months will be given to the patients to progress the exercises, with patients progressing as per their ability.

Outcomes will be repeated at 3 months, and at the end of treatment or at 6 months (whichever is sooner). At the end of treatment, the initial 16 patients who received pre intervention EMG studies will receive EMG studies to look at whether muscle activity has changed. At 12 months post treatment the outcome scores will be repeated again.

Compliance with the physiotherapy regime

As compliance with physiotherapy exercises is likely to affect outcomes, the treating physiotherapist will ask patients at each visit 'how many days in the last week have you completed your exercises?'
This will be documented in the physiotherapy notes as a number (0-7). If the patient answers 5 or above they will be considered as compliant. At each assessment this will be documented on the case report form as compliant yes or no.

Withdrawal from the Study

Patients may withdraw from the study at any time. Their data will be withdrawn from the study. At each visit the patients consent will be sought for continuation in the study. If a patient loses capacity they will be withdrawn from the study.

Expected Side Effects that are known to occur after Steroid injection

Facial flushing can occur it settles without any treatment

Very rarely anaphylaxis can occur, this is a serious emergency. The injections are being performed in a clinic environment, exactly the same as if they were being given for clinical reasons so the patient is at no more increased risk. The means to manage such a rare emergency are present as

they would be for usual clinical practice. With usual supportive treatment, the patient would not be expected to have any long term effects.

Some patients may have a episode of vasovagal following injection. As the injection is being given in clinic the patient is in the same environment as if not part of the trial and being given an injection.

The pain may take a week to subside after injection. This is normal.

Safety reporting and pharmacovigilance

The following definitions are in accordance with both the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031) and the subsequent amendment regulations (SI2006/1938) and ICH-GCP.

Adverse Event (AE): Any untoward medical occurrence in a clinical trial participant to whom an IMP has been administered and which does not necessarily have a causal relationship with the treatment. An AE can therefore be any unfavourable and unintended sign (including abnormal laboratory finding), symptom, or disease.

Adverse Reaction (AR): Any noxious and unintended response in a clinical trial participant to whom an IMP has been administered, which is related to any dose administered. A "response" to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. The relationship cannot be ruled out.

Serious Adverse Event (SAE): Any adverse event that:

- Results in death
- Is life-threatening*
- Required hospitalisation or prolongation of existing hospitalisation**
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect
- Other medically important condition***

The term "life-threatening" in the definition of serious refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure, for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened or elective procedures does not constitute an adverse event.

Other events that may not result in death are not life threatening, or do not require hospitalisation may be considered as a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

Serious Adverse Reactions (SARs): Any Serious Adverse Event occurring in a clinical trial participant for which there is a reasonable possibility that it is related to the IMP at any dose administered.

Suspected Unexpected Serious Adverse Reactions (SUSAR): These are SARs which are classified as 'unexpected' i.e. an adverse reaction, the nature and severity of which is not consistent with the information about the medicinal product outlined in the SPCs for Bupivacaine or Kenalog (triamcinolone acetonide).

AE recording and reporting will start at the time of consent for each patient and end when each patient ends the trial. SAEs will be reported to the sponsor within 24hours of an investigator becoming aware of the event.

For the purposes of this study we will not be recording any serious adverse events that are related to pre existing medical conditions of these patients or adverse events/SAE related to expected events associated with IMP administration or physiotherapy treatment.

<u>Statistical and data collection</u>

The outcomes of VAS, constant and oxford scores will be analyzed between the intervention (injection of steroid and local anesthetic) and control (injection of local anesthetic only) groups.

Statistical advice was sought from Dr Nick Taub (Research Fellow in Medical Statistics, University of Leicester). A power analysis was performed to assess the number of patients required for the study using the basis that a mean

treatment effect between treatment groups of at least 6 points on the oxford shoulder score is of clinical benefit to patients. Using this data a study of 35 patients recruited into each group (70 in total) will have an 80% power to detect this effect at the 5% level of significance assuming that no more than 20% of recruited patients will be lost to follow up and that the within group standard deviation in Oxford Shoulder Score change to 12 months is 7.93(taken from Ainsworth(shoulder and Elbow 2009;1:55-60)

There is relatively little data on EMGs and rotator cuff tears, and such as there is in cross sectional studies. Data from Kelly (2005) indicate that statistically significant differences can be found in muscle activation patterns between symptomatic and asymptomatic cuff tears with 6 patients in each group. So we are starting with 16 patients. Descriptive data on EMGs will be discussed, comparing pre and post treatment activation patterns, and also comparing patterns in those who improved significantly and those who did not. The EMG data will be analysed after the 16 patients have had pre and post physiotherapy EMGs. If it looks as if more patients will give further information we may recruit sequential patients at the end of the study for increased numbers. Therefore this part of the study is a pilot study.

The descriptive data from the ultrasound scans regarding the position of the tear will also be discussed, and related to the success of treatment for all patients.

Data will be entered into excel and then analysed using SPSS-PC.

Ethics approval will be sought and obtained prior to the study commencing.

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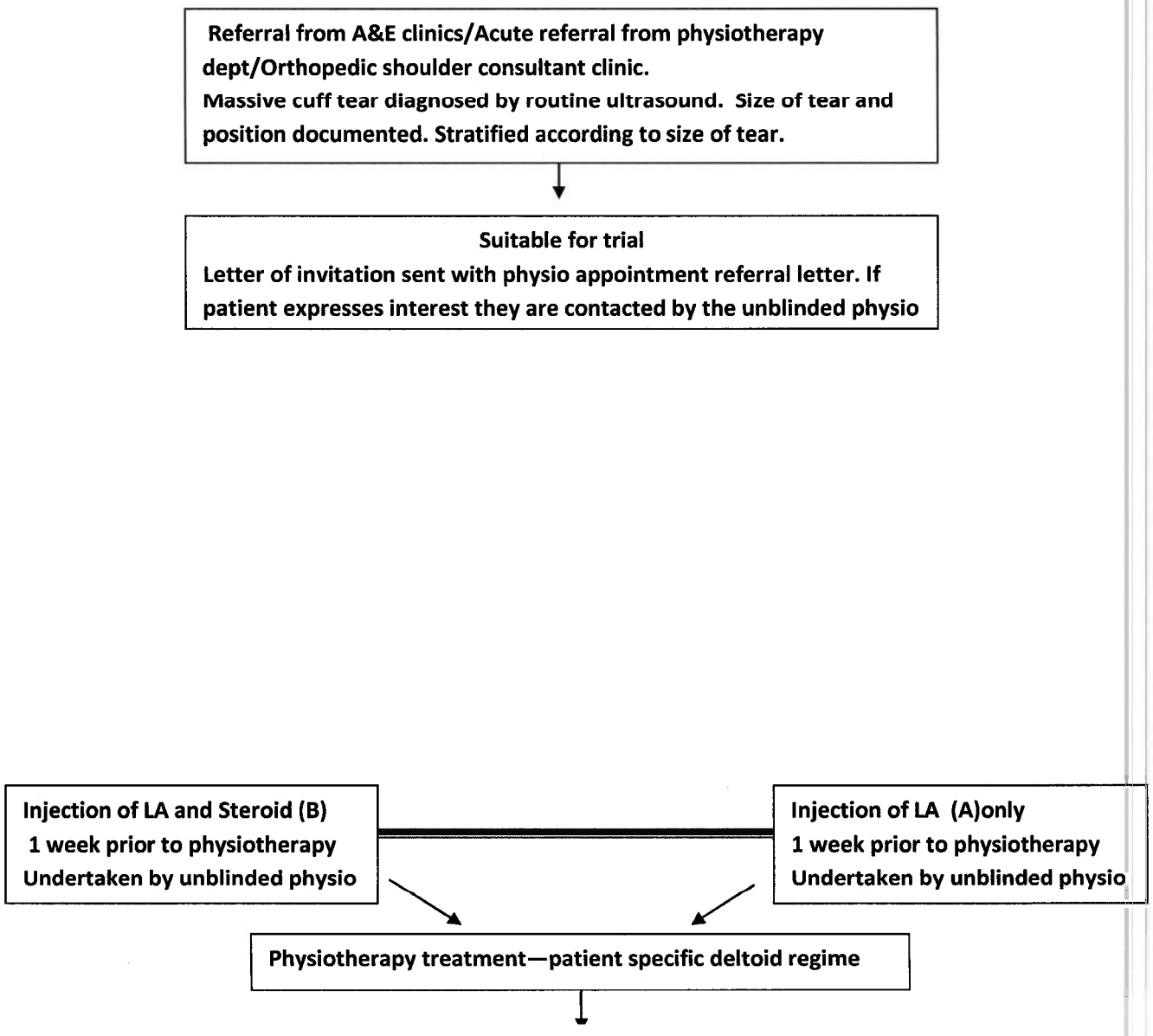
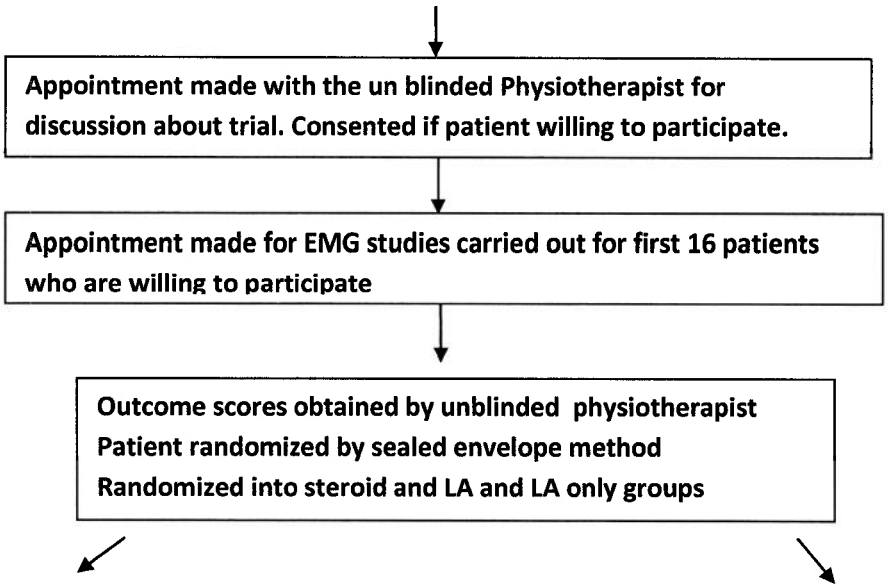
Appendix 1
FLOW CHART TO EXPLAIN THE ORDER OF INVESTIGATION AND TREATMENT




Appointment made with the un blinded Physiotherapist for discussion about trial. Consented if patient willing to participate.
Appointment made for EMG studies carried out for first 16 patients who are willing to participate
Outcome scores obtained by unblinded physiotherapist
Patient randomized by sealed envelope method
Randomized into steroid and LA and LA only groups