

**tITLE OF THE PROTOCOL:**

**E**ar**L**y **E**xercise in blunt **C**hest wall **T**rauma: a feasibility trial (ELECT Trial)

**Short title/Acronym: ELECT study**

**Sponsor: Swansea Bay University Health Board (SBU HB)**

Representative of the Sponsor:

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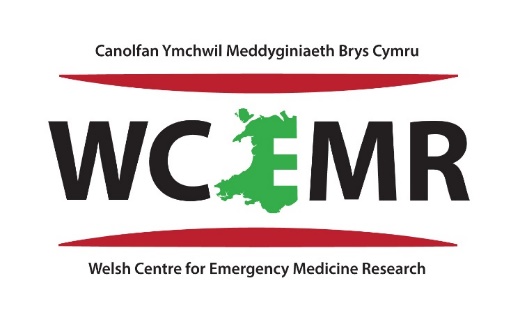
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**REC reference:**



**STUDY SUMMARY/SYNOPSIS**

|  |  |
| --- | --- |
| **TITLE** | EarLy Exercise in blunt Chest wall Trauma: a feasibility trial (ELECT Trial) |
| **SHORT TITLE** | ELECT study |
| **Protocol Version Number and Date** | Version 1.1 10th March 2019 |
| **Methodology** | Feasibility. Interventional |
| **Study Duration** | 6 months |
| **Study Centre** | Morriston Hospital, SBU HB |
| **Objectives** | This feasibility trial will have two primary objectives:  1) To assess the sample size requirements and attrition rates for a full randomised control trial and recruitment period needed to achieve this target  2) To test the feasibility and acceptability of the proposed trial methods; including the parallel randomised controlled design, the recruitment and consent processes, and collection of the proposed outcome measures at pre-specified time points. |
| **Number of Subjects/Patients** | No specific target. Three month recruitment period |
| **Main Inclusion Criteria** | 1) Patients who have sustained isolated blunt chest wall trauma admitted to Morriston Hospital for >24hours  2) Patients aged 18 years or more with capacity to consent and complete survey |
| **Statistical Methodology and Analysis** | Pre-set trial feasibility criteria will be assessed using a traffic light system (in which green means the target was achieved, amber means the target was not achieved but progression is possible with some minor protocol modifications, and red means progression to a full trial is not possible). |

**Protocol Agreement Page**

The clinical study as detailed within this research protocol **(Version 1.1, dated 10th March 2019)**,or any subsequent amendments will be conducted in accordance with the Research Governance Framework for Health & Social Care (2005), the World Medical Association Declaration of Helsinki (1996) and the current applicable regulatory requirements and any subsequent amendments of the appropriate regulations.

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# Glossary of Terms and Abbreviations

AE Adverse Event

AR Adverse Reaction

ASR Annual Safety Report

BCWT Blunt chest wall trauma

CA Competent Authority

CI Chief Investigator

CRF Case Report Form

CRO Contract Research Organisation

DMC Data Monitoring Committee

EC European Commission

GAfREC Governance Arrangements for NHS Research Ethics Committees

ICF Informed Consent Form  
ISRCTN International Standard Randomised Controlled Trial Number

MA Marketing Authorisation

MS Member State

Main REC Main Research Ethics Committee

NHS R&D National Health Service Research & Development

PI Principal Investigator

QA Quality Assurance

QC Quality Control

Participant An individual who takes part in a clinical trial

RCT Randomised Controlled Trial

REC Research Ethics Committee

SAE Serious Adverse Event

SDV Source Document Verification

SOP Standard Operating Procedure

SSA Site Specific Assessment

TMG Trial Management Group

TSC Trial Steering Committee

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1. **INTRODUCTION**

**1.1 Background / 1.2 Preclinical Data**

Blunt chest wall trauma accounts for over 15% of all trauma admissions to Emergency Departments (ED) worldwide, with reported mortality ranging between 4 and 60%.[1] The most common injury mechanisms include low velocity falls (>2m), high velocity falls (>2m), road traffic accidents, assaults and sporting injuries. Over 1800 patients presented to the Emergency Department in Morriston Hospital in 2017 with blunt chest wall trauma. Difficulties in the management of blunt chest wall trauma patients in the ED are becoming increasingly well recognised in the literature.[2] Historically, analgesia and chest physiotherapy have been advocated as the primary methods of managing a patient with blunt chest wall trauma, with the main aim of reducing the acute risk of the development of potentially fatal pulmonary complications.[3]

**1.3 Clinical Data**

Longer-term complications have also been investigated and in a small study conducted by this research team, chronic pain was reported in 35% patients with a median pain severity score of 6 out of 10 (IQR: 3–7).[4] In a similar recent prospective study of 111 patients with isolated rib fractures, a prevalence of chronic pain of 64% and disability of 67% were reported.[5] In a 2019 study, chronic pain and disability were reported in 62% and 57% of patients at 3 months post injury respectively.[6] If over 1800 patients are presenting to one ED in Wales per year with blunt chest wall trauma, with a prevalence of 57-67% disability at two to three months post injury, this highlights a major healthcare problem which is not currently being addressed in clinical practice. Patients are simply discharged home with no follow-up care. Clinicians are traditionally taught that the pain and disability of rib fractures resolves in six to eight weeks.[5]

What remains unknown in blunt chest trauma literature, is the best management for addressing the longer-term complications, specifically chronic pain and disability. The overall aim of this phase of work, is to investigate whether early thoracic and shoulder girdle exercises improve chronic pain in blunt chest wall trauma patients, when compared to normal care (where normal care traditionally involves chest physiotherapy techniques such as breathing exercises and early mobilisation / walking and no thoracic / shoulder girdle exercises). This work will support the key objective of the Welsh Government’s plan for “A Healthier Wales”, which states that we want services which support people to stay well, not just treat them when they become ill. If the trial is successful and early exercise is shown to be beneficial in reducing chronic pain in this large patient cohort, then the programme can be shared throughout Wales using the newly established Welsh Trauma Network (which aims to share good practice across the country ensuring that we identify and support the best new models of health and social care so they scale up more quickly to the whole of Wales, as set out in the Healthier Wales plan)

**1.4 Rationale and Risks/Benefits**

There are no known risks involved with participation in this feasibility interventional study. Patients will be asked to complete a number of thoracic and shoulder girdle exercises, which will be supervised by a qualified physiotherapist responsible for the patient’s overall care. The potential benefit of the study is that the feasibility study will achieve the progression criteria and the future full RCT can be developed in which the exercise programme improves BCWT patients’ longer-term outcomes.

**2.** **TRIAL OBJECTIVES AND DESIGN**

**2.1 Trial Objectives**

We aim to establish the feasibility of a future definitive parallel RCT comparing the use of early thoracic and shoulder girdle exercise for the management of blunt chest wall trauma patients versus normal care.

This feasibility trial will have two primary objectives:

1) To assess the sample size requirements and attrition rates for a full randomised control trial and recruitment period needed to achieve this target

2) To test the feasibility and acceptability of the proposed trial methods; including the parallel randomised controlled design, the recruitment and consent processes, and collection of the proposed outcome measures at pre-specified time points.

**2.2 Trial Design**

*Design*

Feasibility interventional study

*Setting and sample*

The study will be single-centred, to be run at Morriston Hospital. All isolated BCWT patients who are admitted for 24 hours or more, over a three month period in 2019, with an additional three month follow-up period (plus one further month to chase up non-responders). Patients will be included in the trial if they have isolated blunt chest wall trauma and can complete the exercises and surveys. Patients with other injuries that could contribute to on-going pain and disability will be excluded.

*Definition of variables*

Blunt chest wall trauma will be defined as a non-life-threatening, isolated injury.

*Study design*

Patients allocated to the intervention group, will receive standard care, in addition to a programme of thoracic / shoulder girdle exercises (delivered by the physiotherapist who would routinely manage the patient as part of standard care). This programme will be continued by the patient, three times per day, for seven days post-assessment. The exercise programme will consist of shoulder active range of movement exercises trunk active side-flexion, rotation, forward flexion and extension range of movement exercises (all within limits of pain).

The control group will receive standard care only. At baseline and at three months post recruitment, participants will be asked to complete the EQ5D-5L in order to assess appropriateness of the outcome measures and potential difficulties in follow-up. Participants in the intervention group will be asked to record compliance with the exercise programme, using a pre-designed proforma.

Pre-set trial feasibility criteria will be assessed using a traffic light system (in which green means the target was achieved, amber means the target was not achieved but progression is possible with some minor protocol modifications, and red means progression to a full trial is not possible).

The survey responses will be entered onto a paper case report form. Any survey with missing demographic data will still be included in the study and the remaining responses included in the analysis. Response rates will be recorded and non-responder analysis will be completed to compare the characteristics of the non-responders and the responders. Patients will be identified only by their hospital numbers once completed surveys are received.

**2.3 Study Scheme Diagram**

**3. SUBJECT SELECTION**

**3.1 Number of Subjects and Subject Selection**

All patients admitted to Morriston Hospital with a length of stay of 24 hours of more fitting the study inclusion criteria, will be approached to participate in the study. The number of patients we aim to recruit to the study will not be pre-defined as this is a feasibility study, instead we will aim to recruit over a three months period.

**3.2 Inclusion Criteria**

* Isolated BCWT patient
* Aged 18 years or more
* Capacity to consent to participation
* Capacity to complete survey
* Length of stay of 24 hours or more

**3.3 Exclusion Criteria**

* Aged less than 18 years
* No capacity to consent to participation
* No capacity to complete survey
* Length of stay of less than 24 hours

**3.4 Criteria for Premature Withdrawal**

* Death
* Patient request for study withdrawal

**4. STUDY PROCEDURES**

**4.1 Informed Consent Procedures**

Informed consent will be obtained by the chief or principal investigators who will all receive ‘protocol and informed consent specific training’ in alignment with the principles of GCP. Consent will be obtained following a full introduction to the study and once the patient has had time to discuss the Patient Information Sheet with a family member / carer (as appropriate). The participants will be given 24 hours to consider participation. A study withdrawal letter will be given to the participant with the Patient Information Sheet, which can be sent to the CI at any time during the trial.

**4.2 Screening Procedures**

All patients admitted to Morriston Hospital with a length of stay of 24 hours or more, fitting the study inclusion criteria, will be screened for potential participation in the study, by the chief or principal investigators. A screening log will be maintained throughout the study period.

**4.3 Randomisation procedures**

Patients will be randomized (patient level) to the trial using a 1:1 ratio, using “Sealed Envelope” ([www.sealedenvelope.com](http://www.sealedenvelope.com)) an independent company which is available 24 hours per day. Moving forward to the main trial, this is the company that will be used. We will consider appropriate confounders which will be included as possible stratification variables for randomization (such as age, sex and injury severity).

**4.4 Follow up Procedures**

At three months post-injury, the patient will be sent a survey in the post. If there is no reply to the postal survey after one month, the CI / PI / research nurse team, will contact that patient and administer the survey by telephone.

**4.5 End of Study Definition**

The study will end when all data has been collected and all surveys are completed.

**4.6 Subject Withdrawal**

A patient can withdraw from the study at any time during the data collection period. They will have a study withdrawal letter that can be sent to the CI at any time.

**4.7 Data Collection and Follow up for Withdrawn Subjects**

Any patient who withdraws consent will have their data removed from the study.

**5. SAFETY REPORTING**

As patients in the intervention group are being asked to complete a new early exercise programme, a contact phone number will be provided in order that they can seek advice if needed. This programme is completed as part of routine practice with the same patient cohort in South Africa, so we do not envisage any complications associated with the exercise programme.

**5.1.1 / 5.1.2 Adverse Event (AE)** **and Serious Adverse Event (SAE)**

The definitions to be used in this feasibility trial are given in Table 1.

**Table 1:**

|  |  |
| --- | --- |
| **TERM** | **DEFINITION** |
| **Adverse Event (AE)** | Any untoward medical occurrence in a patient or clinical trial patient to whom a study intervention or procedure has been administered including occurrences which are not necessarily caused by or related to that intervention. |
| **Serious AE (SAE)** | Respectively any adverse event that:   * Results in death (death is an outcome not an event) * Is life-threatening a * Requires hospitalisation or prolongation of existing hospitalisation b * Results in persistent or significant disability or incapacity * Consists of a congenital anomaly or birth defect   Other important medical condition c |
| **Unexpected Adverse Event (UAE)** | A Serious Adverse Event, the nature and severity of which is not consistent with the information known about the intervention |

**a** The term “life threatening” in the definition of “serious” refers to an event in which the patient 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.

**b** Hospitalisation is defined as an impact admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition (including the development of pulmonary complications post-chest injury) do not constitute an SAE.

**C** Medical judgement should be exercised in deciding whether an AE is serious in other situations. The following should also be considered serious: important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above.

**5.1.3 Adverse events that will be recorded**

The following AEs are expected in the context of this trial and will only be recorded as outcomes on the appropriate CRF:

* Emergency or delayed insertion of a pleural or intercostal chest drain for an underlying lung pathology caused by the chest wall trauma (pneumothorax, haemothorax, effusions)
* Need for surgical fixation and any associated (surgical) complications
* Development of pulmonary complications as a result of the blunt chest wall trauma (on-going pain pulmonary contusions, chest infection / pneumonia, pneumothorax, haemothorax, effusions, empyema, sepsis)
* Hospitalisation: admission to a ward for observation, any mode of pain control, physiotherapy, antibiotic administration, oxygen therapy
* Hospitalisation: admission to the High Dependency Unit / Critical Care Unit for observation, any mode of pain control, physiotherapy, antibiotic administration, oxygen therapy, non-invasive or invasive ventilation.
* Surgical intervention: any patient with a severe blunt chest wall injury will be considered for surgical fixation of the chest wall.

During the trial period, any diagnostic, therapeutic or surgical procedure performed as part of both standard and unscheduled care should be recorded including the date of occurrence, description of the procedure(s) and any clinical findings.

Patients with severe blunt chest wall trauma are at increased risk of death. All deaths will be assessed for expectedness. However, should any of these events meet the criteria for an SAE (Table 1) they must be reported on an SAE form and uploaded to the trial database within 24 hours.

**5.1.4 Serious adverse events that require expedited reporting**

All SAEs must be reported by the PI to the CI within 24 hours of knowledge of the event by using paper SAE forms. Confirmed SAEs will be reported by the CI on behalf of the Sponsor to the REC within 15 days of knowledge of the event by the CI. The CI will inform the local R&D department / sponsor.

All deaths will be assessed for expectedness. Patients with severe blunt chest wall trauma are at increased risk of death so most will not be classified as a SUSAR.

**5.2 Investigators assessment**

All SAEs will be assessed by the CI (or other person authorised to do so on the delegation log) in respect of causality and expectedness to determine whether the SAE is a SUSAR. SAE duration and severity will also be assessed for SAE form completion, as required.

**5.2.1 Seriousness**

The Investigator should make an assessment of seriousness as defined in Table 1.

If the event is serious, unexpected and not exempt from expedited reporting, then an SAE form must be completed on the trial database within one working day of the PI being informed of the event.

**5.2.2 Causality**

The Investigator must make an assessment of whether the SAE is likely to be related to the intervention according to the following definitions:

* Unrelated: where an event is not considered to be related to the trial intervention
* Possible: although a relationship to the trial intervention cannot be completely ruled out, the nature of the event, the underlying disease, concomitant medication or temporal relationship make other explanations possible
* Probable: the temporal relationship and absence of a more likely explanation suggests the event could be related to the trial intervention
* Definitely: the knowledge of the event indicates that the trial intervention is the most likely cause.

All safety events judged as having a reasonable suspected causal relationship (e.g. possibly, probably, definitely related) to the trial intervention will be considered SAEs or UAEs. Alternative causes such as natural history of the underlying diagnosis, other risk factors should be considered.

**5.2.3 Expectedness**

The Investigator must evaluate the expectedness of all SAEs and the knowledge they have of the event. If the event is classified as serious, related and unexpected, the event is a Suspected Unexpected Serious Adverse Reaction (SUSAR) and must be reported by the CI within 24 hours.

For unexpected SAEs which do not have a causality decision, they should be reported as “potential SUSARs” within 24 hours by the CI with later downgrading to an SAE where relevant.

**5.2.4 Severity**

The Investigator must assess the severity of the event according to one of the following categories:

* Mild: an event that is easily tolerated by the participant, causing minimal discomfort and not causing disruption of daily activities.
* Moderate: an event that is sufficiently discomforting to cause disruption of daily activities
* Severe: an event that prevents normal daily activities

**5.3 Notification and reporting adverse events and serious adverse events**

1. The SAE must be added to the SAE log in order to assign an SAE number to the event. The number should be the next available SAE number for that participant on the log. That number will be used on the SAE form to identify the SAE for that participant.

2. The SAE form should be completed as thoroughly as possible with all available details of the event by the CI within 24 hours of knowledge of the event. The Investigator (or deputy named on delegation log who is responsible for the patient’s care), with due care being paid to the grading, causality and expectedness of the event outlined above or delegate, should assess, complete and sign to confirm all entries are accurate.

3. If all required information is not available at time of reporting the site team must ensure that missing information is completed on a follow up SAE form and entered on the database as soon as available.

4. Follow up; participants must be followed-up until clinical recovery is complete or until the event has stabilised. If necessary, follow-up should continue after completion of protocol treatment. Follow-up information will be noted on the database.

5. All SAEs will also be filed in the participant’s notes, in addition to the Investigator Site File.

6. Confirmed SAEs will be reported by the CI to REC and sponsor within 15 days of event knowledge as per approval conditions.

7. In the event of a SUSAR, the PI must complete the SAE form within 24 hours indicating as much details as possible for the expectedness and causality information to justify their assessment. If one of these is unknown, the SAE should be reported as a “potential SUSAR” within 24 hours of the event by entering the SAE form onto the trial database

8. The CI will provide quarterly safety update reports for all SAEs to the sponsor and trial sites.

9. The CI (or delegate medical expert) will review all SAE reports received. The causality assessment given by the local Investigator at the hospital will be reviewed by the CI. The Investigators decision cannot be overruled and in the case of disagreement, both opinions will be provided in any subsequent reports.

**5.4 Annual Safety Reporting**

The CI will be responsible for the completion of an Annual Progress Report to the REC using the applicable ethics template. This report will be due every 12 months after the date of the favourable opinion by the REC. The Annual Progress Report will also be sent to the Sponsor.

**6. STATISTICAL CONSIDERATIONS**

As this is a feasibility trial, we will not conduct any primary analysis of outcomes. Pre-set trial feasibility criteria will be assessed using a traffic light system (in which green means the target was achieved, amber means the target was not achieved but progression is possible with some minor protocol modifications, and red means progression to a full trial is not possible). Feasibility criteria will include:

***Primary feasibility outcomes:***

1) Adherence with the protocol by physiotherapy team – no less than 80% of patients recognised as eligible patients by study physiotherapists are randomised

2) Acceptability of trial to patients – dissent to take part in the study is 30% or less

***Secondary feasibility outcomes:***

3) Retrieval of outcomes - Follow-up data for primary outcome suitable for fully powered trial (EQ5D-5L) can be collected for 70% or more of patients

4) Safety - There should be no greater than 10% increase in serious adverse events in the intervention group compared to the control group

**6.1 Sample Size**

We will not have a specific target sample size, but will recruit over a period of three months. The purpose of this is to test the feasibility of the future trial methods, rather than investigate any differences in clinical outcomes. In a six month period (June to December 2018), a total of 72 patients with blunt chest wall trauma were admitted for more than 24 hours to a major trauma unit in South Wales

We do not know at this stage what our main outcome measure will be. As this is a feasibility study, we plan to collect data on quality of life and pain outcomes, using the EQ5D-5L survey. We will use this information to determine whether the data can be collected and what the most appropriate outcome for the main study will be. We will use data collected from patients in the feasibility study to inform the fully powered study in terms of:

a) Specifying the most important outcome

b) Deciding what the smallest clinically significant difference for that outcome which we plan to detect in the main trial

c) Deciding on the power which we wish to detect that difference (at a reasonable level of statistical significance)

**6.2 Statistical Analysis**

Data will be analysed using descriptive statistics; numbers (%) mean (SD) / median (IQR). Pre-set trial feasibility criteria will be assessed using a traffic light system (in which green means the target was achieved, amber means the target was not achieved but progression is possible with some minor protocol modifications, and red means progression to a full trial is not possible).

**7. DATA HANDLING AND RECORD-KEEPING**

**7.1 Confidentiality**

The CI will take responsibility to ensure that patient anonymity is protected and maintained. The CI will also ensure that their identities are protected from any unauthorised parties. Information with regards to study patients will be kept confidential and managed in accordance with the Data Protection Act, NHS Caldicott Guardian, The Research Governance Framework for Health and Social Care and Research Ethics Committee Approval.

All patients will be allocated a study number once informed consent is obtained. Personal data will only be identifiable by this study number during data collection. Data collection will only include demographics and survey responses. All patient identifiable data will be removed and data completely anonymised once data collection using the survey is completed. Data will be stored on a Health Board, password encrypted computer, only accessible to the CI / PIs of the study team. The CI will act as the custodian of the data. The Caldicott Guidelines will be adhered to throughout the study.

**7.2 Study Documents**

A copy of the patient consent form, Patient Information Sheet, study withdrawal letter and case report form is attached to this submission. A Trial Management file will be used and all hard copies (as listed below), will be kept in a locked room within the physiotherapy department.

* A signed protocol and any subsequent amendments
* Sponsor Self-Monitoring template for the trial team to complete on a regular basis as detailed by the Monitoring section
* Current/Superseded Patient Information Sheets (as applicable)
* Current/Superseded Consent Forms (as applicable)
* Indemnity documentation from sponsor
* Conditions of Sponsorship from sponsor
* Conditional/Final R&D Approval
* Signed site agreement
* Ethics submissions/approvals/correspondence
* CVs of CI and site staff
* Delegation log
* Staff training log
* Site signature log
* Patient identification log
* Screening log
* Enrolment log
* Monitoring visit log
* Protocol training log
* Correspondence relating to the trial
* Communication Plan between the CI/PI and members of the study team

**7.3 Record Retention and Archiving**

During the course of research, all records will be the responsibility of the Chief Investigator and will be kept in secure conditions. Once the research trial is complete, the records will be kept securely for a further 5 years in the Health Board archive facility.

**7.4 Compliance**

The CI will ensure that the trial is conducted in compliance with the principles of the Declaration of Helsinki (1996), and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework, Trust and Research Office policies and procedures and any subsequent amendments.

**7.5 Ethical Considerations**

This protocol and any subsequent amendments, along with any accompanying material provided to the patient in addition to any advertising material will be submitted by the Investigator to an Independent Research Ethics Committee. Written Approval from the Committee must be obtained and subsequently submitted to the Research & Development Department to obtain Final R&D approval.

**7.6 Summary Monitoring Plan**

The Research Governance Manager will monitor this study in accordance with Health Board Policy. Although a risk based monitoring assessment will often build in flexibility for monitoring activities, ICH E6 R2 requires sponsors to periodically review their risk control measures to ascertain whether the quality management activities that have been implemented remain effective and relevant. The results of monitoring may direct changes to the monitoring assessment/strategy; either moderation (downgrading of activities) or escalation of activities. The Quality Assurance Officer can alter the monitoring visit timeframes depending on the monitoring findings.

A Quality Assurance programme is in place to ensure adherence to the protocol. Major and minor deviations will be collected. Each visit will verify that the rights and wellbeing of participants are protected. Accuracy, completion and validity of reported trial data from the source documents, evaluation of the conduct of the trial with regards to GCP, compliance with the currently approved protocol, and within the applicable regulatory requirements will also be verified.

**7.7 Audit and Inspection**

**Auditing**: Definition “A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).”

This study may be identified for audit by any method listed below:

1. A project may be identified via the risk assessment process.

2. An individual investigator or department may request an audit.

3. A project may be identified via an allegation of research misconduct or fraud or a suspected breach of regulations.

4. Projects may be selected at random. The Department of Health states that Trusts should be auditing a minimum of 10% of all research projects.

5. Projects may be randomly selected for audit by an external organisation.

Internal audits will be conducted by a sponsor’s representative

**7.8 Non-Compliance**

Each Quality Assurance visit will verify that the rights and wellbeing of participants are protected. Accuracy, completion and validity of reported trial data from the source documents, evaluation of the conduct of the trial with regards to GCP, compliance with the currently approved protocol, and within the applicable standard operating procedures (SOP’s).

Non-compliances may be captured from a variety of different sources including monitoring visits, CRFs, communications and updates. The sponsor will maintain a log of the non-compliances to ascertain if there are any trends developing which need to be escalated. The sponsor will assess the non-compliances and action a timeframe in which they need to be dealt with. Each action will be given a different timeframe dependent on the severity. If the actions are not dealt with accordingly, the R&D Office will agree an appropriate action

**8. Trial Committees**

There will be no Trial Steering Committee or Data Management Committee set up for this study

**9. Publication Policy**

The aim would be to publish the results of this study in an emergency medicine journal and present the results in a trauma / emergency medicine conference.

**10. References**

1) Battle CE, James K, Hutchings H, et al. Risk factors for the development of complications in blunt chest wall trauma: a retrospective study. Injury 2013;44:1171-6.

2) Battle CE, Hutchings H, Evans PA. Risk factors that predict mortality in patients with blunt chest wall trauma: A systematic review and meta-analysis. Injury 2012;43:8-17.

3) Battle CE, Hutchings H, Evans PA. Blunt chest wall trauma: a review. Trauma. 2013;15(2):156-175.

4) Battle C, Young K, Evans PA. Chronic pain in blunt chest wall trauma: an observational study. Trauma; 2016 DOI: 10.1177/1460408616638689

5) Fabricant L, Ham B, Mullins R et al. Prolonged pain and disability are common after rib fractures. The American Journal of Surgery (2013) 205, 511-516

6) Carrie C, Guemmar Y, Cottenceau V et al. Long-term disability after blunt chest trauma: don’t miss chronic neuropathic pain. Injury 2019;113-118.

**11. Appendices**

**Appendix 1 – Information with regards to Safety Reporting in Non-CTIMP Research**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Who** | **When** | **How** | **To Whom** |
| **SAE** | Chief Investigator | -Report to Sponsor within 24 hours of learning of the event  -Report to the MREC within 15 days of learning of the event | SAE Report form for Non-CTIMPs, available from NRES website. | Sponsor and MREC |
| **Urgent Safety Measures** | Chief Investigator | Contact the Sponsor and MREC Immediately  Within 3 days | By phone  Substantial amendment form giving notice in writing setting out the reasons for the urgent safety measures and the plan for future action. | Main REC and Sponsor  Main REC with a copy also sent to the sponsor. The MREC will acknowledge this within 30 days of receipt. |
| **Progress Reports** | Chief Investigator | Annually ( starting 12 months after the date of favourable opinion) | Annual Progress Report Form (non-CTIMPs) available from the NRES website | Main REC |
| **Declaration of the conclusion or early termination of the study** | Chief Investigator | Within 90 days (conclusion)  Within 15 days (early termination)  *The end of study should be defined in the protocol* | End of Study Declaration form available from the NRES website | Main REC with a copy to be sent to the sponsor |
| **Summary of final Report** | Chief Investigator | Within one year of conclusion of the Research | No Standard Format  However, the following Information should be included:-  Where the study has met its objectives, the main findings and arrangements for publication or dissemination including feedback to participants | Main REC with a copy to be sent to the sponsor |