ISRCTN95571506 https://doi.org/10.1186/ISRCTN95571506

A feasibility study evaluating a risk score for the management of blunt chest wall trauma

Submission date
05/12/2016

Recruitment status
No longer recruiting

Registration date
05/12/2016

Overall study status
Completed

Last Edited
01/08/2019

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In 2014, in Morriston Hospital in Swansea, 1038 patients with rib injuries (blunt chest trauma) visited Accident and Emergency (A&E). A total of 100 of these patients were admitted to hospital and 13 of these patients died. It can be difficult for doctors in A&E to manage patients who have injured their ribs. A patient will often develop respiratory infections such as pneumonia, but not until approximately 72 hours after they have injured themselves. Doctors need to be able to decide which patients can be sent straight home from A&E, or which patients need to go to a ward or to the Intensive Care Unit (ICU). If the doctor makes the wrong decision, the patient who was sent straight home may develop pneumonia. There would then be a delay in good patient care such as strong pain relief, antibiotics and physiotherapy. This might mean that the patient dies and this has been known to happen. Over the last six years, a simple risk model has been developed and validated that calculates a risk score that the doctors in A&E can then use to decide which patients will develop pneumonia. It also helps the doctor decide where the patient should be managed (for example should they be sent home or go to a ward or to ICU?). In the long term, the aim is to investigate the effectiveness of this risk score. In order to do this, it is necessary to assess whether it helps doctors make the right decisions for patients by making sure they are cared for in the most appropriate place and that they get better as quickly as possible, and if the score saves the NHS valuable resources and money. This aim of this study is to complete a small study to find out whether the different aspects of the main study would be feasible.

Who can participate?
Adult patients with blunt chest trauma who go to A&E of a participating hospital.

What does the study involve?
There are four hospitals taking part, each of whom will collect data for a number of months not using the risk model (just usual care) and then a number of months using the risk model. All patients will be recruited to the trial over a five month data collection period. In both periods, when a patient is admitted to A&E with blunt chest trauma they are asked by the doctor to take part in the study. The patient then is asked to complete a consent form and a short survey. The doctor then either does or does use the risk score to assess the patient (depending on which data collection period they are in). A research nurse then records information about the

patient's hospital stay (if they are admitted). At the end of the study, the number of participants that take part and how well doctors are able to use the risk score is recorded in order to see whether conducting a larger study would be feasible.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
The study is run from Morriston Hospital, Swansea and Swansea Medical School, Swansea University, and takes place at:
1. Royal Gwent Hospital (UK)
2. Musgrove Park Hospital (UK)
3. Manchester Royal Infirmary (UK)
4. Salford Royal Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2016 to September 2018

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact?
Dr Ceri Battle
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32652

Study information

Scientific Title
A multi-centre randomised feasibility STUdy evaluating the impact of a prognostic model for Management of BLunt chest wall trauma patients: STUMBL Trial

Acronym
STUMBL

Study objectives
Over the last six years, the background research, development and external validation of a new prognostic model has already been completed and all work has been both published and presented internationally. The aim of this study is to establish the feasibility of the final definitive impact trial, which will ultimately determine whether the prognostic model can be used safely and effectively in clinical practice in Wales and the rest of the UK. If this feasibility trial progresses to the full impact trial, the new prognostic model could improve the prudent healthcare of blunt chest wall trauma patients, through the reduction in the number of post-injury complications, an improvement in quality of life at six weeks and an overall improvement in cost-effectiveness of patient management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committe 6, 27/09/2016, ref: 16/WA/0290

Study design
Multi-centre cluster randomised feasibility trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Injuries and emergencies, Primary sub-specialty: Musculoskeletal Trauma; UKCRC code/ Disease: Injuries and Accidents/ Injuries to the thorax

Interventions
There will be four hospitals participating in the trial, which will be run using a stepped wedge design. In this design, all hospitals will commence data collection at the same time, as the control arm (usual care with no model). Every month, following the initial month's data collection period as controls, one hospital will be randomly assigned to become an intervention arm (using model) sequentially, until all hospitals are acting as interventions. The randomisation process applies to the hospitals (known as clusters) participating in the trial, rather than at a patient level. As there are four hospitals participating in the trial, all patient recruitment will be completed over a five month period. This trial design will test the feasibility of the classic stepped wedge design, to be used in the future definitive trial.

The only difference in interventions between the two study arms will be the use of the risk model, which will only be used in the treatment arm. In both arms, the following process will occur:
The patient will present to the ED with blunt chest trauma. They will be assessed for trial eligibility by the ED clinician and then recruited / consented to the trial as appropriate. Once informed consent is given, the patient will complete the quality of life survey on initial assessment in the ED. The doctor will then use the risk score to manage the patient (in the treatment arm only). A research nurse will then complete the data collection during the patient's hospital stay (if admitted only). This data collection will focus on patient outcomes such as admission location, length of stay, mechanical ventilation days and whether the patient develops any pulmonary complications or needs an upgrade in care). Patient follow up will occur at six weeks post-injury, when the patient will be asked to complete two short surveys. At that point, the patient's involvement in the trial will end.

Intervention Type
Other

Primary outcome measure
Patient recruitment rate will be recorded as the number of eligible patients who consent to trial participation at the end of the five month data collection period, at each site.

Secondary outcome measures
1. Clinician recruitment rate will be recorded as the number of eligible clinicians working within the participating ED who agree to take part in the study by the end of the five month data collection period, at each site
2. Response rate of follow up data (quality of life surveys) will be recorded as the number of patients returning postal surveys at the end of the five month data collection period, at each site
3. Clinicians Training Attendance rate will be recorded as the number of clinicians receive formal training in the use of the model, prior to the second data collection period (treatment arm), at each site
4. Compliance with use of model rate will be recorded as the number of times the clinician used the risk model for an eligible patient, at the end of the second month data collection period (treatment arm)

5. Overall mean quality of life as reported using the SF-12v2 survey for patients, at the end of the control (end of month two) and treatment (end of month five) data collection periods, at each participating site
6. Resource usage by patients as a results of the intervention as reported on the Client Service Receipt Inventory at six week follow-up

Overall study start date
01/10/2016

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Diagnosis of isolated blunt chest wall trauma
2. Aged 18 and over
3. Capable of giving consent to participation
4. Male or female
5. Presenting to the Emergency Department of participating hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Four clusters/hospitals, with 30 to 80 patients in each cluster (120-320 patients in total)

Total final enrolment
176

Key exclusion criteria
1. Patients under the age of 18 years
2. Patients who lack capacity to give informed consent,
3. Patients with any immediately life-threatening injuries
4. Patients with any concurrent injury that will determine the patient’s management (rather than the chest trauma)

Date of first enrolment
01/01/2017

Date of final enrolment

31/10/2017

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Musgrove Park Hospital
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
Manchester Royal Infirmary
Grafton Street
Manchester
United Kingdom
M13 9WL

Study participating centre
Salford Royal Hospital
Stott Lane
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
ABMU Health Board

Sponsor details
Morriston Hospital
Morriston
Swansea
Wales
United Kingdom
SA6 6NL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Results and Publications

Publication and dissemination plan
Dissemination of the outputs from this trial is proposed through publication in an appropriate Emergency Medicine journal and by presentation at relevant international conferences. We will publish the protocol for the trial in a scientific peer reviewed journal. The aim of this feasibility trial is not to report definitive results regarding clinical and cost effectiveness however, any important outputs produced in the study related to the prognostic model will be published in appropriate Emergency Medicine Journals, as follow-on articles from our previous published work in this area. We will disseminate our findings to stakeholders via professional meetings. The results of the study will also be published in the Trauma Audit Research Network (TARN) monthly newsletter, received by all participants contributing to TARN working in the EDs in the UK and some countries in Europe. We will disseminate the outputs of this feasibility trial to other research infrastructure groups such as PRIME Centre Wales (the Wales Centre for Primary and Emergency Care Research). All outputs will be discussed with the clinicians involved in the study through the writing up of a research report. Any patients who have expressed an interest in receiving study results during the recruitment process will also be sent the report.
The overall expected output of the future definitive impact trial (the methods / infrastructure of which this feasibility trial is testing) is evidence that the prognostic model is acceptable for use in the clinical setting. It is hoped that it will be widely accepted and used in the EDs in England

and Wales to assist in the management of this patient group. The overall aim is for the model to be considered for inclusion in future NICE guidelines for the management of blunt chest trauma patients. Furthermore, if the impact trial results are positive, it could be possible to attempt to validate the model for use in primary care. This patient group could then be effectively managed by the GP or Minor Injuries Unit who would be able to easily assess whether the patient needs admission to hospital.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/07/2017	01/08/2019	Yes	No
Results article	results	26/07/2019	01/08/2019	Yes	No
HRA research summary			28/06/2023	No	No