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Is it possible to conduct a study to compare using and not using a rigid neck collar to immobilise the neck in adults who have potentially injured the spinal cord in their neck?

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
04/02/2020

Overall study status
Completed

Last Edited
03/09/2021

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cervical spinal cord injury (SCI) means an injury to the spinal cord, a bundle of nerves that runs the length of the spine from the brain to the tailbone and is protected by the vertebrae (the bones in the spine), in the neck. This can be a very serious and life-changing injury, because if the spinal cord is severed, a person can be paralysed in their whole body below the injury. Therefore it is important not to move the spinal cord too much if there are broken vertebrae that might damage the spinal cord.
Within the UK, SCI is rare. The current practice if there is the possibility that someone has an SCI is to wrap a rigid collar around the neck and secure it with tape to keep their neck still. The collar is kept on until the patient has reached hospital and has had an SCI ruled out, usually after a scan. The collar can be uncomfortable or even painful and can restrict the patient's breathing. It can also add to their anxiety when they are already in a stressful situation. Using a collar has been the standard clinical practice for over 50 years. However, there is little evidence to show whether this is necessary or not. The practice has become so ingrained within trauma management culture that it is difficult to change. New research suggests that it might be better not to use the collar by default in all situations where a potential SCI is suspected and to allow paramedics and doctors to use their judgment to tailor the method of immobilisation to the patient and situation.
This study aims to investigate whether it is possible and practical to run a larger study that will investigate whether it is better to use a rigid neck collar in every case or not.

Who can participate?
Adults who have had an injury where an SCI might occur (such as a road traffic collisions, a falls from height or a serious assault), who have symptoms suggestive of SCI and who are being transported by the North East Ambulance Service to Northumbria Specialist Emergency Care Hospital or James Cook University Hospital .

What does the study involve?
Depending on which hospital the patient is being taken to, they will have the collar put on or not. When they have been stabilised at the hospital and are able to give consent, participants will be asked whether information can be taken from their medical records for the purposes of the study and whether they are willing to fill in a questionnaire about their experience of spine immobilisation.
The participating clinicians will also be asked to undertake an experience questionnaire.

What are the possible benefits and risks of participating?
As the current practice is that the collar is used, there are no additional risks of participating in the study associated if the participant has the collar put on, since they would have the collar if there was no study underway. The benefits of the collar are the potential prevention of worsening of the SCI and that it acts as a visual reminder to healthcare professionals that the patient might have an SCI so they need to take care when treating and moving the patient. The potential risks of the collar are delays in getting the patient into the ambulance, breathing complications, discomfort, agitation, worsening of the spinal injury and injuries to the skin and soft tissues where the collar contacts the body.
The benefits of not using the collar are that the risks from using the collar do not apply. The risk is that there will be no visual reminder to staff of the potential SCI.

Where is the study run from?
North East Ambulance Service (UK)

When is the study starting and how long is it expected to run for?
January 2018 to September 2021

Who is funding the study?
The National Institute for Health Research (NIHR), North East Ambulance Service NHS Foundation Trust and Prometheus Medical Ltd (all UK)

Who is the main contact?
Lee Thompson, lee.thompson@neas.nhs.uk

Study website
https://www.neas.nhs.uk/our-services/research-and-development/smrf.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
253128

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42132, IRAS 253128

Study information

Scientific Title
Spinal Motion Restriction Feasibility (SMRF) study: A prospective, randomised, two-centre, comparative study to determine if there is a difference in clinical outcomes and patient experience comparing Spinal Motion Restriction techniques which include the traditional use of a rigid cervical spine collar versus the omission of a rigid collar.

Acronym
SMRF

Study objectives
The Spinal Motion Restriction Feasibility (SMRF) Study is a prospective randomised two-centre comparative study. It is a study to determine if there is a difference in clinical outcomes and patient experience comparing Spinal Motion Restriction techniques which include the traditional use of a rigid cervical spine collar verses the omission of a rigid collar during management of potential spinal cord injury.
Within the United Kingdom (UK), traumatic Spinal Cord Injury (SCI) is a rare event. Traditional three-point immobilisation for spinal stabilisation has been the standard clinical practice for trauma patients with suspected cervical SCI for over 50 years. Although emotive, the evidence for traditional immobilisation practices is equivocal.
Contemporary literature and consensus reports are now challenging the traditional practices that may potentially cause more harm to patients when managing traumatic SCI in favour of pragmatic and supportive techniques that follow patient centred spinal motion restriction principles.
The SMRF Study will recruit adult patients who have been assessed as having a potential SCI in the pre-hospital environment originating from an acute traumatic incident. The two branches of the trial will include the same assessment and management pathways but will differentiate

between using a rigid cervical collar and omitting the use of a rigid collar but maintaining spinal support through manual or self-supporting methods.
Patients will be recruited by pre-hospital ambulance clinicians and transported to one of two participating NHS Emergency Departments where follow up will occur to obtain clinical outcomes and undertake a participant experience questionnaire. Clinicians will also undertake an experience survey.
The study is expected to recruit for 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/03/2020, North East – Newcastle & North Tyneside 2 Regional Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 104 8138; nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net), ref: 20/NE/0055

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Process of Care, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
See additional files.

Health condition(s) or problem(s) studied
Use of a rigid collar in patients who have a potential cervical spinal cord injury following trauma

Interventions
Participants will be pre-randomised based on the hospital sites they are attending. Initially the two participating sites will be randomised to either intervention or control site. After 6 months duration the sites will reverse and whichever site was originally randomised as intervention site will become the control site for the remaining 6 months and the control site will become the intervention site. The participants will be selected by the attending trained North East Ambulance Service (NEAS) personnel and enrolled into the study if they are positive for a mechanism of injury and clinical assessment that would suggest a Spinal Cord Injury.

Control group: Over a 3-month period this group will be managed in the traditional manner. This will involve patients being advised of the need for a hard collar, blocks and tape. For a variety of reasons this may not be tolerated by some patients and this non-compliance will be recorded for the purposes of the study outcome results, although these patients will be included in the 'traditional' method of motion restriction numbers.

Intervention group: Over a 6-month period, intervention group patients transported by NEAS crews with a suspected cervical spine injury being taken to the randomised intervention site will have their cervical spine motion restriction managed with the omission of a rigid collar. For these patients, unless the exclusion criteria apply, no hard collars will be employed.

After the initial 6-month intervention/control phase the receiving sites will reverse the process and undertake another 3-month phase as the control/intervention phase.

Each participant enrolled will be followed up on-site by a research clinician and clinical outcomes measured as stated on the Computerised Tomography (CT) report and/or patient notes. Patient experience outcomes will be collected by a research clinician using a dementia-friendly adapted Likert scale type survey prior to discharge or at 72 h whichever is earliest . Participants will also be consented at this point. It is expected that only one visit will be required unless participants wish to delay consent to consider the information.

Data will be collected in a Microsoft Excel spreadsheet and analysis will be undertaken using Statistical Package for the Social Sciences (SPSS) version 22.0.

Free text from the patient experience questionnaire will be transcribed and analysed using NVIVO.

Description of statistical methods:
The primary analysis will be by intention to treat, comparing the outcomes between all participants randomised to Intervention (non-collar) and all those randomised to Control (normal practice). The focus of the analysis will be on estimation of treatment effects and the uncertainty around them. A detailed statistical analysis plan will be developed by the trial statistician.

Results will be presented as estimates of the treatment effect with 95% confidence intervals. Dichotomous outcomes will be analysed using logistic regression models, both unadjusted and adjusted for appropriate covariates. Time to event outcomes such as time on-scene or time to CT will be analysed using time to event techniques. Continuous outcomes will be analysed by regression methods and the results presented as the difference in means between the groups and 95% confidence intervals. Reporting of analyses will follow CONSORT guidelines.
The following exploratory analyses will be used to investigate potential modifiers of the treatment effect of non-collar use:
• Age
• Mechanism
• Compliance

Interim analysis:
The Data Monitoring Committee will monitor the accumulating outcome data, and one of their roles is to recommend cessation of recruitment if a clear result has been reached (i.e. if either intervention or control is clearly superior). We suggest that different thresholds of evidence for early termination are adopted if non-collar or collar being more effective, as it is likely that stronger evidence would be needed to change current practice (collar use) if non-collar use is found to be superior. We therefore propose that interim analyses are conducted frequently in the early stages of the trial, so that, if collar use is superior, this can be detected early. Thus we will minimise any risks to patients while producing robust evidence that will change practice.

Sample size:
This will be a feasibility study and as such an underpowered study with no power calculations. It is expected that if the results are favourable then a full multi-centred clinical trial will follow.

As such, a sample size of 50 participants per site will be expected over the 12-month study period (N=100) as well as 100 prehospital clinicians who will be recruited for a participant experience questionnaire. It is unknown how many participants will drop out of the study, however, due to a single study visit it is believed that there will be a very low drop-out /withdrawal rate.

Analysis of Outcome Measures:
Describe analysis of primary and secondary outcome measures. Include details as to which participant data will be used (e.g. all participants, including/excluding those that withdrew consent, or have been un-blinded).

Randomisation:
Within the context of this study it is almost impossible to blind the intervention/control to either the participants or clinicians carrying out the intervention/control because of the type of equipment used.

There are two receiving sites within the study. One will be randomised to being either the intervention site for the first 6 months followed by 6 months as the control site. The other receiving site will therefore be randomised as the opposing site acting as the control site for the first 3 months followed by the intervention site for 3 months.

The two sites will be randomised as either:
1. Intervention (6 months) followed by control (6 months) or
2. Control (6 months) followed by Intervention (6 months).

To assist in this randomisation the online tool 'Research Randomizer' will be used.

Bias:
One of the major potential sources of bias in randomised trials is inclusion of different patients in the arms of the trial. This can arise where a large proportion of potentially eligible patients are not included in the trial, and the probability of inclusion is related to the intervention. In this study we aim to identify and include close to 100% of the eligible patients, using a combination of methods for identifying eligible patients, including direct notifications by ambulance clinicians and review of routine ambulance service data.

Threshold for intervention:
As ambulance clinicians delivering the interventions will not be blinded, there is a possibility that bias could be introduced by different thresholds between the intervention group (no rigid collar) and control group (standard care including rigid collar). If they believe strongly that non-collar use is effective, some of them may attempt spinal motion restriction without using the collar for patients who are not appropriate, excluded from the study or in the control group of the study and therefore inappropriate. This would result in a group of patients being inappropriately recruited or excluded from the trial potentially masking any beneficial or negative effect of non-collar use. We will use several strategies to prevent this bias from occurring, to detect it if it happens, and to correct it if necessary.
First, the criteria that are used to determine whether spinal motion restriction is appropriate, and hence whether the patient is eligible, are as objective as possible. The guidance used by all participating ambulance clinicians in the study to determine when spinal motion restriction is

appropriate/not appropriate will continue in the trial. Ambulance clinicians will already be familiar with the application of these criteria, and no change of practice will be needed during the trial with the exception of including those participants over the age of 65 years who have had a mechanism of injury potentially causing injury and complaining of any pain or discomfort in the neck area.

Second, all ambulance clinicians in the study will be trained in the study procedures, to ensure that they understand the rationale for the study and the importance of following the study procedures correctly. The training will include a review of existing evidence so that participating ambulance clinicians understand the current position of equipoise regarding the effectiveness of rigid collars, and discussion of potential sources of bias in the study and the importance of applying the inclusion/exclusion criteria rigorously to both arms. Training will continue throughout the recruitment period, to ensure that any new staff are trained before recruiting, and that important messages are continually reinforced.

Third, we will institute a programme of regular monitoring by analysing the characteristics of patients recruited to the intervention group (non-collar) and control group (standard care including rigid collar) and the proportion of potential spinal cord injured patients recruited, to detect any imbalances that may be caused by different thresholds for spinal motion restriction. If a lower threshold for attempting spinal motion restriction in the intervention group (non-collar use) exists we will find a greater number of recruits and a greater proportion of incidents with spinal motion restriction attempts. The frequency and mechanism of monitoring will be discussed with the Data Monitoring Committee.

If we suspect that a different threshold for spinal motion restriction is being applied by any personnel recruiting to the study, the first step will be to identify the personnel involved and ensure that their training in the trial procedures is up to date, and reinforce the essential messages about the rationale for the trial. The investigators will develop close working relationships with the ambulance clinicians recruiting patients, and will be ideally placed to undertake this role.
Finally, we can, if necessary, correct for any inclusion bias in the statistical analysis of the study, by adjustment of the analysis to take account of imbalance in factors such as mechanism of injury and time since 999 call. We expect any potential inclusion bias to affect only the group of patients least likely to have any detrimental outcomes, and it would not affect patients for whom spinal motion restriction would always be undertaken and therefore a comparison between intervention group (non-collar) and control group (standard care including rigid collar) in the subgroups of patients in whom spinal motion restriction is known to be appropriate would be unaffected.

Crew Preferences:
A potential source of bias is that ambulance clinicians who are motivated to not use the rigid collar may avoid using it during the control phase of their participation in the study. In order to check for this possibility, we will monitor crews attending incidents that are potentially managed with spinal motion restriction and investigate any suspicious patterns such as non-compliance with the allocated treatment. If found, the staff involved will be given extra training in the study procedures.

Blinding:
Due to the nature of the interventions, ambulance clinicians cannot be blinded, and will be aware of treatment allocations. Ambulance emergency operation centre dispatch personnel will be blinded to the allocation of the ambulance service vehicles, to ensure that there is no bias in whether a vehicle with a study trained clinician (intervention or control) or non-study vehicle is

sent to an incident that is likely to involve spinal motion restriction. Patients themselves will be aware of their treatment allocation at the time of the intervention. Research clinicians assessing outcomes at the receiving hospitals not be blinded to treatment group due to the contents of the patient notes and liaising with the patients during their in-hospital phase who were not blinded.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Time in minutes from paramedics' arrival on scene to time leaving scene (on-scene time) assessed using North East Ambulance Service EMS 999 automated vehicle resource log. Data extrapolated within 7 days of incident.
2. Time in minutes from arrival in Emergency Department to the patient receiving a cervical spine imaging in the Emergency Department assessed using North East Ambulance Service EMS 999 automated vehicle resource log and date/time stamp on CT/imaging report (Care Stream). Data extrapolated within 7 days of incident.
3. Presence of gross neurological changes initially assessed by Emergency Department staff as a baseline using the NICE 2016 guidelines (https://www.nice.org.uk/guidance/ng41/resources/spinal-injury-assessment-and-initial-management-pdf-1837447790533). This data is reported within the trauma document.
4. Presence of fractures or other physiological injury as reported in trauma assessment and imaging reports within 7 days of assessment/imaging and reported within Care Stream and the trauma document.
5. Severity of pressure ulcers or other tissue viability problems assessed using the International NPUAP EPUAP Pressure Ulcer Classification System within the Emergency Department assessed and reported within the nursing notes of the trauma document prior to discharge from Emergency Department.
6. Participant compliance assessed and reported (compliant/non-compliant) by clinician during initial management at time of application/non-application of collar and reported within the electronic patient care record (Safe Triage)

Secondary outcome measures
All secondary outcome measures will be recorded using a participant experience questionnaire scored using a Likert scale within 72 h.
1. Comfort during neck immobilisation
2. Pain during neck immobilisation
3. Understanding of procedure
4. Complications (e.g. anxiety, breathing difficulties)

Overall study start date
16/01/2018

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Aged 18 years and older
2. Transported by North East Ambulance Service crew to either participating Emergency

Department
3. Any of the following conditions apply:
3.1. Participant has had a mechanism of injury and clinical assessment suggestive of SCI. Example mechanisms include (but are not exclusive to) road traffic collisions, falls from height and serious assaults. In the elderly or frail patient, this may include a fall from standing height and should be based on a thorough clinical exam
3.2. Participant has symptoms consistent with cervical spine injury. For older patients any neck pain, including muscular, should be considered as suspicious for cervical spine injury.
3.3. Participants with dementia/delirium who are unable to communicate reliably regarding potential injury and have significant head injury, as they are at risk of potential cervical spine injury and should be included in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Total final enrolment
59

Key exclusion criteria
1. Requires airway support for whatever reason
2. Glasgow Coma Score < 13 (reduced conscious level)
3. Displaying obvious signs of new neurological injury, such as paralysis
4. Significant facial injuries that may benefit from the support a rigid collar may provide
5. Already immobilised with a rigid collar by a non-study clinician or third party provider prior to intervention group clinician assessment

Date of first enrolment
10/08/2020

Date of final enrolment
09/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Marton Rd
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United Kingdom
TS4 3BW

Sponsor information

Organisation
North East Ambulance Service NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.neas.nhs.uk/

ROR
https://ror.org/02mphet60

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North East Ambulance Service NHS Foundation Trust

Funder Name
National Institute for Health Research (NIHR)

Funder Name
Prometheus Medical Ltd

Results and Publications

Publication and dissemination plan
An initial report will be provided to the Sponsor (NEAS) and research sites (NSECH & JCUH). Planned publication in a high impact peer-reviewed journal is expected by 30/09/2022.

Intention to publish date
30/09/2022

Individual participant data (IPD) sharing plan
The 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?
Participant information sheet	version v1.1	24/01/2020	04/02/2020	No	Yes
Participant information sheet	version v1.1	24/01/2020	04/02/2020	No	Yes
Protocol file	version v1.1	24/01/2020	04/02/2020	No	No
HRA research summary			28/06/2023	No	No