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Stabilising the spine following traumatic injury: a randomised controlled trial

Submission date
21/12/2022

Recruitment status
Recruiting

Registration date
24/01/2023

Overall study status
Ongoing

Last Edited
04/08/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Cervical spine (c-spine) injuries often occur as a result of road traffic crashes, sports injuries or as a result of falling in frail people. Although c-spine injuries are rare, if they do occur, they can have a dramatic effect on an individual's quality of life and can lead to long-term disability or even death. In the UK, when a potential c-spine injury occurs, the ambulance paramedics will usually stabilise the spine in one of two ways. Either, they will place the patient on a rigid board or mattress and strap across their forehead using tape supported by blocks and/or a hard neck collar. This reduces any movement, to prevent more damage to the spine during transfer to the hospital. This is known as triple spinal immobilisation. There is some concern that this can harm more than it helps patients. For example, causing difficulty in breathing, skin or brain injury or in rare instances making a spinal injury worse. Or, they will alter this slightly to introduce some flexibility, so that the patient is more comfortable and there may be fewer side effects. This is called movement minimisation. Currently, both of these immobilisation methods are used in the UK as normal practice, and patients can be given either method when their spine needs stabilising, but we don't know if movement minimisation will worsen spinal problems (such as paralysis) or improve potential complications of triple immobilisation such as breathing in vomit (aspiration), skin problems and brain injury. In this situation, it is common to do a clinical trial.

Who can participate?
Patients who require spinal immobilisation by NHS Ambulance Service staff

What does the study involve?
There is no more treatment needed in the trial and the patient will continue to receive the normal care required. The next phase of the trial focuses on the patient's recovery. A member of the hospital, ambulance or Imperial College London research team will contact the patient to discuss the trial further and answer any questions. To understand more about which of the two immobilisation methods should be used to treat patients in the future, and about aspects of your recovery, patients are asked to consent to:
1. Contact to ask some questions about their recovery and to complete a questionnaire during their hospital stay, at discharge, and 30 and 180 days after the date of injury. This will be with a member of either the hospital or Imperial research team and should take between 15-30 minutes.

2. Allow the collection and use of information about their health and recovery, including any identifiable information from routine health records/sources and a national database called the Trauma Audit and Research Network (TARN).
Complex data will be collected from patients across the country. The identifiable information will be kept safe and secure, will only be used in the way specified, and will be destroyed at the end of the trial. In the unfortunate event that a patient subsequently loses capacity after agreeing to take part in the trial, we will approach a personal consultee such as a family member to ask them to complete the questionnaires for them. If we are unable to contact a consultee, we will not send out any questionnaires but will continue to collect information on your health and recovery from medical records and routine health sources.

What are the possible benefits and risks of participating?
There is no direct benefit to taking part in the trial, but it will provide information that will help to treat patients with suspected spinal injuries better in the future. There are no additional risks of taking part in this trial, as both methods of spinal immobilisation are already used as normal practice in the UK.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
October 2021 to May 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
SIS Trial Manager, sis@warwick.ac.uk

Study website
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/sis/

Contact information

Type(s)
Principal Investigator

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Prof Mark Wilson

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316755

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54490, IRAS 316755

Study information

Scientific Title

Randomised controlled trial of the clinical and cost-effectiveness of cervical spine immobilisation following blunt trauma (SIS trial)

Acronym
SIS

Study objectives
The primary hypothesis is that movement minimisation (intervention) is deemed no worse compared to triple mobilisation (control) in patients with potential c-spine injury following blunt trauma, in relation to motor function at hospital discharge following randomisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/12/2022, Health and Social Care Research Ethics Committee B (Office for Research Ethics Committees Northern Ireland (ORECNI), Business Services Organisation, Unit 5, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn BT28 2RF, UK; +44 (0)2895 361408; recb@hscni.net), ref: 22/NI/0173

Study design
Randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Paramedicine

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Injuries and accidents

Interventions
This trial is a prospective randomised non-inferiority trial which means we will study patients who, according to current guidelines require cervical spine immobilisation, randomly assigning them to the two treatment arms - standard triple immobilisation (using a collar) or movement minimisation (using foam blocks and tape to minimise movement). The trial will involve multiple ambulance services and hospitals. We aim to enrol 8316 patients (4158 in each arm of the trial). This is a "non-inferior" study which aims to find out if movement minimisation is "no worse" than the current standard triple immobilisation.

The primary outcome measure is a Functional Independence Measure of motor function (i.e. what participants can physically do) at the time of hospital discharge. The secondary measures include the effects of immobilisation regarding analgesia requirements, neurological change, mortality, length of stay, quality of life and other safety outcomes such as pressure sores and aspiration pneumonia which traditional cervical immobilisation is believed to cause. Patients will be randomised on scene and then followed up in the hospital, at the time of discharge / 30 days and at 180 days (6 months) post-injury.

There will be an initial pilot study recruiting 800 participants in the first 6 months of the trial. Following successful recruitment, the pilot will continue into the main trial.

Intervention Type
Other

Primary outcome measure
Level of disability in terms of burden of care measured using the total Functional Independence Measurement motor (FIM-motor) score at hospital discharge and at 30 days post-injury

Secondary outcome measures
Secondary effectiveness outcomes:
1. Level of disability measured using FIM-motor score at discharge, 30 days, 180 days after randomisation at video clinic or follow-up appointment
2. Level of disability and cognition measured using the total FIM-total score and cognition scales at discharge, 30 days and 180-day at video clinic or follow-up appointment
3. Sensory and motor levels measured using the American Spinal Injury Association (ASIA) impairment scale from randomisation to discharge
4. Mortality measured using patient medical notes at days 30, 90 and 180
5. Intervention for cervical spinal cord injury in the first 30 days or discharge measured using patient medical notes for use of collar for > 2 weeks, halo brace, and cervical spine surgery from randomisation to discharge
5. Discharge destination measured using patient medical notes at discharge
6. Pre-hospital analgesic requirements measured using patient medical notes from the Ambulance Patient Report Form onwards

Secondary safety outcomes:
Adverse events (pressure sores, aspiration pneumonia, intracranial hypertension) measured using patient medical notes from randomisation to discharge

Other secondary outcomes:
Primary Health Care System benefit measure:
Resource use including intervention, hospital (ICU, HDU and ward days) and community costs (primary care and social care costs) in the 6 months following the intervention. Resources will be costed using national reference unit costs where available, reflated to current prices.

Secondary Health Care System benefit measures measured using patient medical notes at the end of the study:
1. Critical care unit length and level of stay
2. Hospital length of stay
3. Re-admissions to the hospital

Utilisation of resource use:
1. Utilisation of community care resources measures using patient medical notes after acute hospital discharge to 6 months after randomisation
2. Health-related quality of life measured using the EuroQol EQ-5D-5L at discharge, 30 days and 6 months

Overall study start date
01/10/2021

Completion date
01/05/2026

Eligibility

Key inclusion criteria
1. Out of hospital with treatment being provided by NHS Ambulance Service staff
2. Patient assessed and found to require spinal immobilisation according to NHS Ambulance guidelines
3. Any Glasgow Coma Score
4. Transfer planned to the participating emergency department

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 2100; UK Sample Size: 2100

Key exclusion criteria
1. Patients not requiring spinal immobilisation according to NHS Ambulance guidelines
2. Patients in whom placing a collar is contraindicated (e.g. pre-existing deformity)

Date of first enrolment
14/06/2023

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
London Ambulance Service NHS Trust
220 Waterloo Road
London
United Kingdom
SE1 8SD

Study participating centre
South Central Ambulance Service NHS Foundation Trust
7-8 Talisman Business Centre
Talisman Road
Bicester
United Kingdom
OX26 6HR

Study participating centre
North West Ambulance Service
Ladybridge Hall
399 Chorley New Road
Bolton
United Kingdom
BL1 5DD

Study participating centre
Isle of Wight NHS - Hq
St Mary's Hospital
Parkhurst Road
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Study participating centre
Welsh Ambulance Services University NHS Trust
Matrix one
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Sponsor information

Organisation
Imperial College London

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Sponsor type
Hospital/treatment centre

Website
http://www.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/05/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Mark Wilson, mark.wilson19@nhs.net and SIS@warwick.ac.uk. Data-sharing plans will be made available at a later date, but it is expected that an anonymised dataset will be available upon the conclusion of the trial.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No