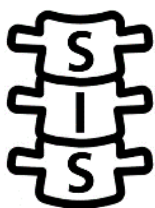


Patient Information Sheet



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

Important things you need to know

- You have been enrolled in the SIS trial, and therefore have been given this information sheet because you were injured, and the attending ambulance service felt your spine needed to be kept still before being taken to hospital for treatment
- Spinal immobilisation is a way of keeping the spine still after an injury, in order to stop any further damage being done
- The ambulance service treating you is taking part in a clinical trial, called Cervical spine immobilisation study following blunt trauma (SIS)
- A clinical trial is a type of research that looks at new treatments or compares existing treatments to improve health and patient outcomes. Clinical trials are carefully designed, monitored and run, and they must be approved before they can start.
- SIS is looking at two methods of holding your spine still, called triple immobilisation and movement minimisation, in order to test whether one method is better than the other. Both of these methods of stabilising the spine are normally used in this type of injury, so even if you had not taken part in SIS, you could have been given either method
- This research will help us improve the care of patients who need their spine stabilising in the future
- The ambulance service staff treating you determined that it was appropriate to enter you into the SIS trial. The decision was made on your behalf, as it was not possible to seek your consent at the time.
- You are being given information about SIS so that you can decide whether you agree to continue in the trial
- You do not have to agree to take any further part in the trial if you do not want to and it will not affect the care you receive
- We will keep all the information about you safe and confidential
- You can choose to stop being in the trial at any time
- Please read this information sheet to help you make your decision

How do I contact the trial team for more information?

University of Warwick Trial Team

Website: <https://warwick.ac.uk/sis>

Email: sis@warwick.ac.uk

Address: SIS Trial Manager, Warwick Clinical Trials Unit,
Warwick Medical School, University of Warwick, Coventry.
CV4 7AL

Hospital Research Team

Name:

Contact details:

What is SIS about?

Why is it important?

Cervical spine (c-spine) injuries often occur as a result of road traffic crashes, sports injury or as a result of a fall 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 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 make 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.

What do we want to know?

We want to work out if one way of stabilising the spine is more appropriate and safer to use than the other way in patients with potential c-spine injury. So, we are conducting a clinical trial involving 2010 patients across the UK.

Key words:

Cervical spine (c-spine) injury: Injury to the cervical spinal cord

Spinal immobilisation: Using strategies and devices to stabilise the spinal column after an injury to prevent damage to the spinal cord

Triple spinal immobilisation: A spinal immobilisation method using a cervical collar, head blocks and tapes to reduce movement

Movement minimisation: A spinal immobilisation method using head blocks and rolled blankets to minimise movement in coronal plane

Taking part in the trial

Why am I already in the trial?

Due to the sudden, unexpected and emergency nature of your injury, you have already had your spine stabilised. Depending on how awake you were, the ambulance staff may have briefly explained the trial to you prior to enrolling you into the trial. But often following a trauma most patients are unconscious and it can be a time-critical and distressing situation, so in these cases it is not appropriate for ambulance staff to explain the trial with you or your family beforehand. Therefore, the ambulance service staff treating you enrolled you in the trial immediately, for this to be discussed with you later.

As part of your treatment, you will have had triple immobilisation or movement minimisation. Because the attending ambulance staff treating you thought you were suitable to receive either form of spinal immobilisation, a computer programme decided which one you received completely at random.

What will happen if I agree to continue to take part?

There is no more treatment needed in the trial and you will continue to receive all the normal care you need. The next phase of the trial focuses on your recovery. A member of the hospital, ambulance or Imperial College London research team will contact you to discuss the trial further and answer any questions you may have. If you do decide to continue in the trial, they will ask you to either physically or digitally sign a consent form to confirm your decision or provide verbal consent (if appropriate). You will be given a copy of the form to keep.

To help us understand more about which of the two immobilisation methods should be used to treat patients in the future, and about aspects of your recovery, we are asking your consent to:

- Contact you to ask some questions about your recovery and to complete a questionnaire during your hospital stay, at your discharge, and 30 and 180 days after your date of injury. This will be with a member of either the hospital or Imperial research team and should take between 15-30 minutes.
- Allow us to collect and use information about your health and recovery, including your identifiable information from routine health records/sources and a national database

called the National Major Trauma Registry (NMTR)). They collect complex data from patients across the country. We will keep your identifiable information safe and secure, will only use it in the way we have specified, and will destroy it at the end of the trial.

In the unfortunate event you subsequently lose 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 you. 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.

Do I have to take part?

You do not have to continue to be in the trial. We understand that some people will not want to complete the follow up questionnaires/assessments or have their routine data collected. If you decide that you do not wish to participate further, this will not affect the treatment or care that you receive in any way.

To make sure that our results are valid and can be relied upon by the NHS to inform how we treat future patients, it is important that we collect other information about your recovery. Therefore, if you do not want to complete the follow-up questionnaires, we would like to continue to collect information about your health from your hospital records and national database. This would not require you to do anything. If you do not want this to happen, it's important that you tell us (using information on page 2) or a member of the research team and we will stop. However, we will normally keep information including identifiable data we have collected about you up to this point. Again, if you do not want us to do this tell us or a member of the research team and we will delete anything we have collected that can identify you as a person.

What are the possible benefits of taking part?

The trial will not be of any direct benefit to you, but it will provide information that will help to treat patients with a suspected spinal injury better in the future.

What are the possible risks of taking part?

There are no additional risks for you taking part in this trial, as both methods of spinal immobilisation are already used as normal practice in the UK, and you could have been given either one whether you were in the trial or not.

What if new or unexpected information becomes available?

There is currently no evidence in this area, which is why the trial is being conducted. If any evidence is published whilst this trial is open, it will be immediately reviewed and the trial stopped if appropriate.

How have patients and the public been involved?

Patient and public representatives have helped us ensure that patient views remain central to the way this clinical trial is designed. Patient and public representatives will continue to

work as part of the research team to help decide how the trial is carried out and how we will look at the results and share them with others.

What will you do with my information?

We will need to use information from you, from your medical records and from the National Major Trauma Registry (NMTR) for this research project.

This information will include your initials, NHS number, hospital number, name, and contact details such as telephone number and email address. People within the College and trial team (see section **'Sharing your information with others'**) will use this information to do the research or to check your records to make sure that the research is being done properly and the information held (such as contact) details is accurate. Our research team at the University of Warwick, and at Imperial College Healthcare NHS Trust will use this information to contact you for the questionnaires or to check your records to collect routine health data and make sure that the research is being completed as planned.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Imperial College London is the sponsor for this trial and will act as the Joint-Controller with University of Warwick. As joint data controllers, both organisations are processing this personal data for the same purpose, have designed this process together and have common information management rules. This means that both organisations are responsible for looking after your information and using it appropriately.

Imperial College London will keep your personal data for:

- 10 years after the trial has finished in relation to data subject consent forms.
- 10 years after the trial has completed in relation to primary research data.

We will keep all information about you safe and secure.

Once we have finished the trial, we will keep some of the data so we can check the results.

We will write our reports in a way that no-one can work out that you took part in the trial.

The study data will then be fully anonymised and securely archived or destroyed.

For more information/confirmation regarding the end date please contact the trial team, see **'Where can you find out more about how your information is used?'** for contact information.

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research trial, we will use your data in the ways needed to conduct and analyse the research trial. Our legal basis for using your information under the UK General Data Protection Regulation (UK GDPR), is as follows:

- Imperial College London – “performance of a task carried out in the public interest”); Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

- Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), The University of Warwick/Imperial College London rely on “scientific or historical research purposes or statistical purposes”.

International Transfers

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research trial or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- the following Research Collaborators / Partners in the trial;
 - The University of Warwick – all data will be shared as joint data controllers
 - National Major Trauma Registry (NMTR) – where appropriate, the following identifiers may be shared with NMTR in order to obtain data about your hospital stay for the purposes of analysis; name, NHS number, date of birth

Potential use of trial data for future research

When you agree to take part in a research trial, the information collected either as part of the trial or in preparation for the trial (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the UK GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

Commercialisation

Data from the trial may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current trial, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique trial number with any data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the UK GDPR) and wider aims of the trial. Your data will not be shared with a commercial organisation for marketing purposes.

What are your choices about how your information is used?

You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone.

- If you choose to stop taking part in the trial, we would like to continue collecting information about your health from central NHS records/your hospital/NMTR. If you do not want this to happen, tell us and we will stop. This will not affect any healthcare or support you may be receiving separately.
- If you choose to stop all information being collected about your health, we will keep the information we have already collected about you up until the day you make that decision. If you decide you want us to delete this, we will delete any information which identifies you as a person that we have collected.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider trial or the accuracy of data collected.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to SIS@warwick.ac.uk, or
- by ringing us on 02476 573005.
- at www.warwick.ac.uk/SIS

Complaint

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to SIS@warwick.ac.uk, or by ringing us on 02476 573005.

Following our response, if you are not satisfied, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

What if there is a problem?

Imperial College London holds insurance policies which apply to this trial. If you experience harm or injury as a result of taking part in this trial, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this trial then you should immediately inform the Research Team. The normal National Health Service mechanisms are also available to you: <https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/>. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

What will happen to the results of the trial?

The trial is expected to take around 2 years to complete, and we're hoping to enrol 2010 participants. We will share the results of the trial with other healthcare professionals and publish the results in medical journals. When any information from the trial is published it will not contain any personal information, and it will not be possible to identify you in any way. We will do our best to make sure the results of the trial are shared widely, and they will be made available on our website at www.warwick.ac.uk/SIS.

Who is organising and funding the trial?

The trial is organised by a group of doctors and scientists led by Professor Mark Wilson who works at Imperial College London. The trial is being coordinated by Warwick Clinical Trials Unit, a registered trials unit at the University of Warwick. The costs of the trial are being met by the National Institute for Health Research (NIHR).

Who has reviewed the trial?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This trial was reviewed and given a favourable opinion by the Office for Research Ethics Committees Northern Ireland (ORECNI) on 2nd of December 2022. The Trial has also been reviewed by the Health Research Authority (HRA) and NIHR.

What happens next?

You do not have to do anything now if you wish to continue taking part. A member of the research team will contact you again soon to discuss this further. You may want to use the space below to note down any questions you may have for them. If you have received this information and do not want to take part in the trial, please fill in the opt-out form attached and send back to the hospital (via email or post) or contact the team via the phone number on the form to inform us of your decision. If we do not receive this form back from you, we will assume you are happy to take part in the trial and to be contacted in the future for follow up calls.

Thank you for reading this information sheet
