Warwick Medical School

University Hospitals Coventry and Warwickshire NHS Trust

Warwick Spinal Immobiliser Trial

Volunteer Information Sheet (phase 2)

1.1 Study title

The Warwick Spinal Immobiliser Trial

1.2 Invitation paragraph

We would like to invite you to take part in our research study. We are testing a new device that can be used to help prevent spinal cord injury following an accident.

Before you decide whether to participate we would like you to understand why the research is being done and what it would involve for you. **One of our team will go through the information sheet with you and answer any questions you have**. We'd suggest this should take about 5-10 minutes.

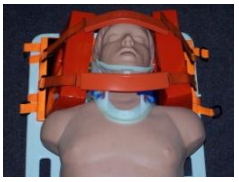
Talk to others about the study if you wish.

(Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

Ask us if there is anything that is not clear.

1.3 What is the purpose of the study?

Traumatic spinal cord injury (SCI) is rare but has devastating consequences on the quality of life of patients and their families. Figures from the UK are difficult to obtain, but we estimate that 0.5 million patients receive spinal immobilisation each year. As modern trauma care appropriately assumes that injury is present until excluded, this creates a huge demand for effective spinal immobilisation.



Current methods usually involve a semi-rigid collar with head blocks and tape (see picture), but we and others have shown that this does not adequately immobilise the neck, allowing movement of the spine risking further injury. The rigid collar prevents opening of the mouth leading to feelings of claustrophobia, and potential danger of inhaling vomit. If the patient stops breathing, the collar must be removed to enable insertion of a breathing tube (intubation), increasing the risk of spinal cord damage. Pressure of the collar on the back of the head can cause pressure sores, and on the root of the neck can increase pressure within the brain (intracranial pressure), worsening any existing head injury.

We have invented a device that we believe may provide better immobilisation without preventing mouth opening, leading to a safer experience for patients. It can be applied before the patient is removed from a vehicle increasing safety for patient and paramedic, and can be left on during X-rays and other investigations.

We believe we have a device that is effective, more comfortable and safer for patients and easier for paramedics to use. We are seeking volunteers who will help us compare it to current methods used for spinal immobilisation. The device is a prototype, and the aim of this study is to test it to prove whether it is better than the devices in current use, and to find ways in which the design can be improved. Ultimately we hope to have a device that can be manufactured and marketed across the UK.

1.4 Why have I been invited?

We are looking for healthy adults to volunteer to test the new device. We shall not be able to include you in the study if you have a known neck problem or history of neck surgery, injury to the neck within the previous 12 months, any condition resulting in restriction of neck movement, or know that you suffer from claustrophobia, or if you have metallic implants, an implantable cardioverter-defibrillator or a pacemaker. We shall also exclude those who are, or may be, pregnant, as the study includes Magnetic Resonance Imaging tests.

1.5 Do I have to take part?

It is up to you to decide whether to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason.

1.6 What will happen to me if I take part?

The design of this device is still confidential, so if you wish to take part in the study we shall require you to sign a consent form that will include the following clause: "I understand that this new device is commercially sensitive, and I commit to keeping all commercially-sensitive information relating to the Warwick Spinal Immobiliser confidential. I understand that this commitment will be valid for a period of seven (7) years or until the information is released into the public domain."

We will provide you with an address for a web page that will explain the study and your potential involvement in it, together with details of how you can contact us by phone or email to discuss the study further. If you are happy to take part and sign the consent form, we will then invite you to a testing session where we will verify that you are willing to participate. The testing session will be in two parts: the first part will involve the testing outlined in sections 1.6.1.1 to 1.6.1.4 below (this will take place during working hours and will last between 60 and 90 minutes), and the second part will involve the MRI scan outlined in section 1.6.1.5 below (this will take place outside working hours at University Hospital Coventry or Rugby St Cross hospital, and will last approximately two hours). You can either take part in both testing sessions, or choose to attend one or the other.

The testing will involve the application of the two spinal immobilisation devices in current use by the UK ambulance services, and our new device in turn, followed by measurement of head movement, tissue pressure exerted by each device, and ability to open the mouth whilst each device is applied. Each of the three devices will be applied by a trained clinician.

1.6.1. Preliminaries

We will be writing a business case for the future use of the device, which will involve recording how long each device takes to apply. The simplest way to capture this is to use a video recorder so that we can use the timings on the video, and capture each stage individually. The video will only be used by the research team, and the footage will only be identified by the ID number of the volunteer.

In order to ensure that the device fits as wide a range of people as possible, we will take and record a few of your measurements. These will be height, weight, neck length and circumference, chest circumference, and measurements of some of the parameters of your head, neck and chest size in order to assess what percentage of the population the new device fits.

We will record the measurements with no device applied, and with each of the three devices applied, whilst you are seated and lying down.

The total time required for all these measurements will be between 60-90 minutes.

1.6.1.1. Measurement of neck movement

This will be done by a trained clinician using a standard device used for measuring cervical range of movement in normal clinical practice (Cervical Range of Movement (CROM) device). The device (see photo) is placed on the head and the angle of movement possible is measured. Each set of measurements will take approximately ten minutes.

1.6.1.2. Measurement of tissue pressure

We will measure the amount of pressure on the skin generated by wearing each of the three devices. This will be done using pressure-sensing transducers embedded in thin mats placed between the device and your body that conform to the curvature of the body. The pressures will be measured simultaneously over the back of the head and jaw whilst you are seated and lying down, and between your shoulder blades and the device whilst lying down.

1.6.1.3. Mouth opening

We will test how far you are able to open your mouth (by measuring the distance between your upper and lower teeth compared to the distance achieved when no device is in place), and how much of your throat is visible with each device in place. .

1.6.1.4. Volunteer experience

We will ask you to complete a questionnaire about your experience of wearing each device. These questionnaires will take approximately five minutes to complete.

1.6.1.5. Magnetic Resonance Imaging

As well as using the CROM device to measure neck movement, we shall also measure the full range of movements using a Magnetic Resonance Imaging (MRI) scan, as this is the only way of visualising the spinal cord. We know that movement of the spinal cord can occur even when the head appears

to be stationary in relation to the shoulders, and we would like to measure this movement using MRI. MRI scanning involves the use of powerful magnets, but does not involve any radiation. It will be performed by a Consultant Radiologist in the imaging department of UHCW NHS Trust (either at Coventry or Rugby). Further information can be found in the patient MRI information leaflet given to you with this document, which has been provided by the imaging department at University Hospital Coventry. See section 1.9 below for further information relating to this aspect of the study.

1.7 Expenses and payments

We will reimburse reasonable travel expenses incurred in you taking part in the above sessions, but no other payment will be made.

1.8 What are the possible disadvantages and risks of taking part?

There is a small chance that the Magnetic Resonance scan mentioned in section 1.6 above might identify a medical problem in your neck that you already have, but of which you were unaware. If this happens, we will take action to ensure that you are referred to the appropriate person for follow-up and treatment if necessary. It is possible that any condition identified in this way may have no clinical significance, or, that finding something incidental at this stage might be of benefit to you.

There are no risks that we can foresee of taking part in the study other than the theoretical risk of a component part of the prototype device breaking during application which might cause minor superficial injury to either the person applying the device or the person to whom it is being applied. The risk of this is very small, the design of the prototype has taken this into consideration, and standard insurance policies will be in place throughout this study. There is a theoretical possibility that cross-infection might occur between you and the previous volunteer to whom the device was applied, but we will ensure that standard cleaning procedures are used to minimise this risk. It is possible that unanticipated risks may occur.

1.9 What are the side effects of any treatment received when taking part?

There are no side effects of taking part other than the small chance of finding out about a condition that already exists, as listed in section 1.9 above.

1.10 What are the possible benefits of taking part?

There are no benefits of taking part other than in helping test what could be a better device to treat people who suffer potential spinal cord injuries in the future. If the MRI scan identifies some pre-existing condition, then it might be an advantage to have this identified and discussed with a medical practitioner earlier than might otherwise have occurred.

1.11 What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

1.12 Will my taking part in the study be kept confidential?

No personally-identifiable data about you will be recorded other than your name, email address and phone number in order that we may keep in touch to arrange visits for testing sessions. This will not be linked to the results of the trial and so your results cannot be identified individually.

We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

2.1 What if relevant new information becomes available?

If new findings arise, or there needs to be a change in the way the study is conducted, or the study is stopped for any reason, we will tell you.

2.2 What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any point. If you do decide to withdraw we would like to keep any data or questionnaires that have been gathered and use them in the analysis of the study. You are at liberty to decline if you so wish.

2.3 What if there is a problem?

If you feel there is a problem with the way the study has been conducted, you should contact the Chief Investigator for the study, Professor Matthew Cooke at the University of Warwick (02476 573164), or the Chair of the Advisory Panel overseeing the study, Professor Sir Keith Porter, Professor of Clinical Traumatology, University Hospitals Birmingham NHS Foundation Trust (0121 371 4955).

2.3.1 Complaints

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (02476 573005). If you remain unhappy and wish to complain formally, you can do this by contacting Ms. Jo Horsburgh, Deputy Registrar, Deputy Registrar, University of Warwick, Research Support Services, University House, Kirby Corner Road, Coventry, CV4 8UW. E-mail: j.horsburgh@warwick.ac.uk Telephone: 024 7657 5686, Fax: 024 7652 4751.

2.3.2 Harm

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Warwick, but you may have to pay your legal costs.

2.4 Will my taking part in this study be kept confidential?

The only personal information collected will be your name, email address and contact phone number in order that we can arrange testing sessions. This will only be available to the Chief Investigator, Project Manager and Ambulance Service Liaison team member, all of whom are employed by the University of Warwick. It will be kept separate from the study data so the two cannot be linked once you have completed your participation in the trial. Transcripts of interviews will be kept in filing cabinets within locked offices in the University of Warwick, or on password-protected or encrypted laptop computers. All data will be kept for five years and then disposed of securely. The only people who will have access to the data will be authorised persons such as researchers, sponsors, regulatory authorities and Research and Development audit (for monitoring of the quality of the research). You will not be identified in any publications or presentations about the trial.

2.5 Involvement of the General Practitioner/Family doctor (GP)

Your General Practitioner will not be informed of your taking part in this study

2.6 What will happen to the results of the research study?

The results of this study will be presented in journals such as the British Medical Journal, and at policy briefings, at national and international conferences and meetings. We will send you a copy of the summary of the final report if you wish. You will not be identified in any report/publication unless you have given your consent.

2.7 Who is organising and funding the research?

The study is being co-sponsored by the University of Warwick and University Hospitals Coventry and Warwickshire NHS Trust, and is funded by the National Institute of Health Research.

The researchers will not be paid for conducting the research (except for their usual salaries), and there are no conflicts of interest for any of the research team.

2.8 Who has reviewed the study?

All research in the NHS is looked at by a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favorable opinion by West Midlands – South Birmingham Research Ethics Committee.

You will be given a copy of this information sheet and a signed consent form to keep.

2.9 Further information and contact details

If you wish to have further information, or have concerns during this study, please contact Professor Matthew Cooke on (02476 573164). For independent advice on this study, please contact Gill Price, Regional Head of Clinical Evidence, West Midlands Ambulance NHS Trust, Millennium Point, Waterfront Business Park, Brierley Hill, West Midlands DY5 1LX. Telephone 01384 246370; email gill.price@wmas.nhs.uk