Warwick Spinal Immobiliser Trial

Paramedic/Technician/Medical Student Information Sheet

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. It will be used as an alternative to the present system of collar, blocks and tape.

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, 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 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 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 you and the patient, 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 easy for paramedics to use. 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. We are seeking volunteer paramedics/technicians who will help us compare it to current methods used for spinal immobilisation, collar/head blocks/tape and the Kendrick Extrication Device.

1.4 Why have I been invited?

We are looking for ten paramedics/technicians and ten medical students who have participated in the Special Study Module in pre-hospital care to be trained to apply the new device to a member of the research team.

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*."

1.6.1. Device application

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 training session. The training session, (a maximum of half a day, but probably much less than this), may be held outside your normal working/lecture hours, and will not result in additional pay. At this session we will verify that you are willing to participate. You will then receive a 10-minute training session on how to apply each of the devices. There will be opportunity to use the new device and discuss its use, and ask further questions. Following a break for coffee, we will then ask you to apply each of the three devices to a member of the research team as you would for a patient. The applications will be videoed so that we can score each application against our checklist of key components of application. Once this is completed, you will be asked to answer a questionnaire that will ask your opinion on the ease of use of each of the devices. All responses from the questionnaire will be anonymised.

Finally, using semi-structured interviews, you will be asked your opinion of the ease of application of each device, together with your suggestions for potential improvements that might be made. The interview will be carried out by one of the research team, will take approximately 10 minutes and will be audio-recorded. The interview will then be transcribed. You will be provided with a copy of the transcript and your permission obtained to use it in the analysis. No personally-identifiable data

about you will be recorded and you will not be identifiable from any of the comments used in the report. We will issue you with a certificate of training for your portfolio.

1.6.2. Device cleaning

We may ask a small subset of paramedics to decontaminate / clean the device as you would do after using it on a patient. The device will then be inspected (and photographed) under UV light to identify how successful the cleaning was. This will allow identification of any 'nooks and crannies' that may harbour blood or other contaminants when the immobilisation device is deployed clinically. We will also ask you to do the same with a traditional collar for comparison.

1.7 Expenses and payments

We will reimburse reasonable travel expenses incurred by you in 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 are no risks that we can foresee of taking part in the study other than the very small 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 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 member of the research team to whom you apply the device, and 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.

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 in the future who suffer potential spinal cord injuries.

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?

See section 2.4 below. 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.

Part 2 of the information sheet

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 from interviews 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, 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 personally identifiable information collected will be your name, email address and contact phone number in order that we can arrange training and 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, 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 favourable 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