Warwick Medical School

Warwick Spinal Immobiliser Trial

Spinally-injured Volunteer 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.

Before you decide 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?

As you know, 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 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 easy for paramedics to use. We have trained paramedics to use the device and 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. Once the first prototype is tested we will consider the results and then redesign the device and create a second prototype that will be tested again. 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 people with recent experience of spinal immobilisation to volunteer to try the new device and to compare it with their experience of collar/head blocks and tape. By recent, we mean within the last 5 years so that you are able to recall your time in a spinal immobiliser in the pre-hospital and/or A&E phase of your care.

1.5 Do I have to take part?

It is up to you to decide whether to join the study. If you require ongoing spinal support as a result of your injury, or wear an appliance for support of any part of your spine, if you have any known instability of any part of your spine, if you cannot transfer without use of some spinal support, or experience pain on movement of your spine, or if you know that you suffer from claustrophobia we will not include you in 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*."

You will be asked to attend a meeting where a trained paramedic or doctor will fit the new device in order for you to give us your opinion on how it compares to your previous experience of collar/head blocks and tape. We will ask you to complete a questionnaire that will cover items such as discomfort, anxiety, and feelings of security after wearing the device for at least ten minutes.

1.7 Expenses and payments

We will reimburse reasonable travel expenses incurred in you taking part in the above session if it is a journey you would otherwise not have made, but no other payment will be made.

1.8 What will I have to do?

See section 1.6 above.

1.9 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 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.

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

There are no side effects of taking part other than that given in section 1.9 above.

1.11 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.

1.12 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.

1.13 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. The questionnaire will be labelled with just your initials, and no results or comments will be individually identifiable.

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 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 573005), 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. Nicola Owen, Deputy Registrar, University of Warwick, Research Support Services, University House, Kirby Corner Road, Coventry, CV4 8UW. E-mail: Nicola.Owen@warwick.ac.uk, Telephone: 024 7652 2785, 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?

No personal information about you will be collected. We will liaise with you via the Spinal Injuries Association who will inform you of when the meeting will take place. The questionnaire will be anonymised and identified only by your initials so that we can contact the SIA to follow up any queries we may have. 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 sponsored by the University of Warwick, 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 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 573005). 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