Warwick Spinal Immobiliser Trial

Anaesthetist 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, potential danger of inhalation of vomit, and difficulty with 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 anaesthetists who will help us compare it to collar/head blocks/tape as the current method used for spinal immobilisation.

1.4 Why have I been invited?

We are looking for a total of 45 anaesthetists to apply the new device to a resuscitation training manikin on an emergency department trolley.

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*."

You will be asked by a member of the research team if you would be willing to assist with this study during a break in normal operating theatre shifts. If you are happy to take part and sign the consent form, we will ask you to undertake an intubation simulation on a resuscitation training manikin in a convenient place within the operating theatre suite. You will carry out the simulation on the manikin with the new device applied, and with collar and blocks applied. For each case you will be presented with a written scenario outlining what you will be asked to do. You will be given opportunity to ask questions for clarification, and will then carry out the intubation; this will be timed and videoed by a researcher. The video recording will be for research team use only, and will provide a back-up of timings if required. We will aim to keep your face out of the recording as much as possible. Following completion of the intubation, we will then ask you to complete a brief questionnaire that will ask you how satisfied you are that you can control the airway without removing the device, and the ease of intubation. All responses from the questionnaire will be anonymised and you will not be identifiable from any of the information used.

1.7 Expenses and payments

None.

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 but standard insurance policies will be in place throughout this study. 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 future patients.

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 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. 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 the 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