STUMBL
STUdy of the Management of BLunt chest wall trauma

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Abertawe Bro Morgannwg University Health Board

R&D RESEARCH & DEVELOPMENT
Abertawe Bro Morgannwg University Health Board

Patient Information Sheet

Study title: A multi-centre randomised feasibility study evaluating the impact of a prognostic model for management of blunt chest wall trauma patients. STUMBL Trial

You are being invited to take part in a research study because you have come to the Emergency Department with an injury to your chest wall. Before you decide if you would like to be involved with our study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully. We will discuss the content of this Patient Information Sheet with you when you see the doctor about your injury.

What is the purpose of the study? There is research that suggests that there are a number of risk factors for longer hospital stays and greater chance of chest infection in patients who have injured their chest wall. It is sometimes difficult for A&E doctors to manage these patients because there are no visible symptoms. A patient may go on to develop pneumonia, but this may not happen until up to 72 hours after they have been injured. Doctors need to be able to decide which patients can be sent straight home from the Emergency Department, or which need to go to a ward or to the Intensive Care Unit (ICU). Over the last six years, we have designed a simple questionnaire that calculates a risk score that the doctors in the Emergency Department can then use to decide which patients will develop pneumonia. The doctor scores the patient on five pieces of patient information which are normally collected as part of your care.

Study aim: In the long-term, the aim is complete a large trial which will test whether our risk score works by helping doctors make the right decisions for patients and whether it saves the NHS resources and money. To successfully complete this large trial in the future, we need to set up a smaller version (feasibility trial) of it. This feasibility trial will help us test out all the different aspects of the large future trial, such as how easy is it to recruit patients, do the doctors use the risk score properly and is it easy to collect the information we need? Information will be collected on patients for two months without using the model and then a further two months using the model.

Why have I been asked to participate? You have been asked to help us as you have come to us with a blunt chest injury.

What will I need to do? If you are happy to help us then all you need to do is sign a consent form to say that you are willing to be involved in the trial. Depending on the stage of the trial the doctor may or may not use the tool but we need your consent to collect your information anyway. The consent form also says that you are willing for us to write your information down and analyse it as part of the study. We would also like you to fill out a short questionnaire today and then again in six weeks. The questionnaire will not take more than 10 minutes to complete.

What are the risks and benefits? There are no known risks associated with this study. The doctor will only use the risk score as a guide, they will still make their own decision regarding where you would be best managed (at home or in hospital) for your injury. The treatment you receive will not be changed in any way. There are no direct benefits for you, but the results of this study may help us treat patients like you in the future.

What happens to me once my information is collected? Your care will be exactly the same as if we were not collecting the information.

What happens if I don't want to participate? You may decline to participate in the study and will be free to withdraw from the study at any time without fear or prejudice. You will still be offered the normal opportunities for treatment available for patients should you need any medical treatment in the future. If you change your mind within the next seven days and want to withdraw from the study, please send the attached form to Ceri Battle (Physiotherapy Dept, Morriston Hospital, Swansea, SA6 6NL). Your details will then be removed from the study.

Confidentiality: Once the information is collected and you have gone home, (and the 7 days have passed in which you can withdraw from the study – see attached withdrawal letter), your name and address will be removed from the information sheet so it is absolutely confidential and anonymous. The information we have collected about you will be stored by the Lead Researcher Ceri Battle who is writing up the study in Swansea where the research team are based, but all your information will be made anonymous and all ethical and legal practice followed to ensure this. It will not be accessible to anyone other than the people in the study team. During the study period, all information sheets will be stored in the same way as medical records and will be kept locked in a filing cabinet. All records will be destroyed as part of the hospitals confidential waste five years following the study. Results of the study may be presented in seminars, teaching sessions and journals but no personal details of anyone participating in the study will be disclosed.

Request for more information: You are encouraged to discuss any concerns you have with the researcher at any time on the contact details below. We are happy to go through all your results with you if you are interested. If you would like to be informed of the results at the end of the trial (end date: September 2018) please contact the chief investigator on ceri.battle@wales.nhs.uk

Who is organising the research and who has reviewed this study? The research is being organised by the clinicians who work for the ABMU Health Board and Swansea University. The study is being sponsored by ABMU Health Board and funded by Health Care Research Wales. This study has been reviewed by the Wales Research Ethics Committee 6.

What if there is a problem? If you have a concern about any aspect of this study you should speak to the researcher who will do her best to answer your questions – Ceri Battle on 01792 703124. If you remain unhappy and wish to complain formally, you can do so through the NHS Complaints Procedure. Details can be obtained from Morriston Hospital switchboard on 01792 702222

Contact details if you need to receive independent advice regarding the study: Mrs Karen James – Team Lead Respiratory Physiotherapist. ABMU Health Board. Morriston Hospital. 01792 703124

Researchers' details

Dr Ceri Battle	Clinical Specialist Physiotherapist, ABMU Health Board
Prof Hayley Hutchings	Professor of Health Services Research, Swansea University, Deputy Director Swansea Trials Unit
Prof Adrian Evans	Professor of Emergency Medicine and Haemostasis, ABMU Health Board
Dr Claire O'Neill	Senior Researcher, Swansea Trials Unit , Swansea University
Dr Sam Groves	Health Economics Researcher, Swansea University
Associate Prof Alan Watkins	Statistician, Swansea University
Professor Fiona Lecky	Clinical Professor Emergency Medicine, Sheffield University