Participant Information Sheet

Efficacy of pressure pad vs pressure bandage immobilisation for snake bite first aid

Protocol number: 109901
Principal Investigator: Dr Adam Holyoak
Co-Investigators: Dr Mark Little, Dr Tyson Reeve, Dr Theophilus Emeto
Location: Queensland X-Ray, Hyde Park, Townsville

Thank you for your consideration of participating in this project which is examining the efficacy of current first aid techniques for snake bite.

What does my participation involve?

Introduction

You are invited to take part in this research project. The research project is testing both the current recommended and alternative treatments for snake bite first aid.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the participant consent form. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Form to keep.

What is the purpose of this research?

There is little data to support the currently recommended first aid treatment for snake bite in Australia. First aid techniques should be simple and easy to use. It has been noticed that people have difficulty in properly using current first aid for snake bite which results in harm. This project aims to look at how effective the current first aid technique is and compare it to a simpler method that is used in other countries. This

information will help improve the care provided to people who have been bitten by a snake and prevent harm occurring from wrongly used first aid treatment.

This project has been initiated by the project doctors, Dr Adam Holyoak, Dr Mark Little and Dr Tyson Reeve. The project is funded by a grant from the Emergency Medicine Foundation.

What does participation in this research involve?

In order to participate in this project, you will first need to be screened to ensure that you are suitable to participate. This will happen when one of the project investigators discusses this information form and what is involved in the project with you and is part of the consent form. The consent form will need to be signed before any of the project assessments will be conducted.

During your participation you will be having a total of six (6) scans. Before each scan you will have an injection of dye (0.2mL in each injection) just below the skin in either your hand or foot. This dye is detected by the scan, which watches how the dye moves inside your body. After each injection, you will have a first aid technique applied before the scan is started. This will involve bandaging of the entire length of the limb that was injected (known as pressure bandage immobilisation) or a small pad of gauze with a bandage at the site of the injection (known as pressure pad). You will also have the injected limb put in a splint to keep it still. These will stay on for up to 1 hour (the entire duration of the scan), and during this time you will need to lie flat on your back and reasonably still (like you would when you sleep). If you are unable to do this, you are not able to participate in the project.

The dye that will be injected is called Technetium-99m sulfur colloid and is a nuclear medicine isotope. This means that it gives off a very small amount of radiation (like what is used in an X-ray). The total dose of radiation you will be exposed to over all six scans of the project is less than the equivalent of 10 chest X-rays (0.6mSv). The dye stays in your body for a period of time, while it breaks down and the body gets rid of it. This period of time is referred to as a half-life and is the time that it takes for one half of the dose to be removed from the body or broken down so that it is not having an effect on your body. A drug is considered to be totally removed from the body after five half-lives. The half-life of Technetium-99m sulfur colloid (the dye that will be used in this project) is 6 hours, and so it may remain active within your body for up to 30 hours. The dose of radiation that you are exposed to over the period of the project includes this time and is based on the dye remaining in your body for 10 half-lives (or 60 hours). The last dose of Technetium-99m sulfur colloid will be completely out of your body before you have your next scan (this is why they are done at least two weeks apart). The dye leaves your body through your kidneys and in your urine, and so over the 2 to 3 days that it takes to leave your body, small amounts of radioactive material will be found in your urine. If other people come into contact with your urine or your other body fluids (for example saliva, faeces, tears) there may be very small amounts of radioactive material present, however the amount is small enough that the effect of potential exposure to this is not considered significant. This means that there is no real risk in close contact with others while you participate in this project.

The total of six scans can occur any time over your participation in the project, but each scan must be at least two weeks apart. If you choose to participate in the project a timetable will be developed for you so you know when you will be having each of these scans. This will be developed with you to fit in with the rest of your life and things that you may have on. The project will run for approximately 2 years, but your participation will only be for the period of time it takes to complete your six scans. For your participation in the project, you will be given a $100 gift voucher when you have completed all six scans, in recognition of the time you have given to participating in the project. You will be responsible for your own travel to and from the study site, and there is free on-site parking. All materials used in the project will be provided for you at no cost.

If you are able to get pregnant, you will be asked to undertake a pregnancy test (which will be provided) before you start each scan. If you are breastfeeding, you are not eligible to participate in this project. Should you become pregnant during the course of the project, you will need to withdraw from participation in the project.

You will be participating in a cross-over study. When we do not know which technique is best for treating a condition, we need to compare different treatments. Because each person may be slightly different, we need to compare these different treatments on the same person at different times and then group all the results together. These results are then compared to see if one treatment is better. The order in which you will receive each treatment will be randomly decided.

What do I have to do?

While participating in the research project you should continue to live your life in the same way you normally do. There are no changes that you need to make to how you live. You should take all your usual medications and eat and drink as normal. If you have any changes in your health, you should let the project team know (and any information you provide will be confidential).

Otherwise, all you have to do is be available for your scans as scheduled, which should take a little over an hour each time, and whatever time it takes you to travel to and from the study site. If you are unable to attend as scheduled, please contact the project team as early as possible so an alternative time can be arranged. During the scans you will be required to lie flat on your back and still (like being asleep) for the entire time of the scan (approximately 60 minutes).

Other relevant information about the research project

Overall, 24 people will participate in this project over the two years that it will run. You will all have the same scans done, but most likely in a different order to any of the other participants. This is the first project of its kind on this topic and the information discovered will help improve the care provided to people bitten by snakes in Australia, but also possibly in other countries around the world.

Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given a Participant Consent Form to sign and you will be given a copy of this Participant Information Sheet to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect any of your routine treatments, your relationship with those treating you or your relationship with the project investigators.

What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research, however you will be helping contribute to the knowledge in this important area of work.

What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. They may be mild, moderate or severe, and may include rash, nausea, itch, fever, and stinging and redness at the injection site. The treatments used in this research project are not known to have any significant side effects but if you have any, or are worried about them, talk with your project doctor. Your project doctor will also be looking out for side effects. There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your project doctor immediately about any new or unusual symptoms that you get. Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your project doctor may need to stop your participation in the project.

Having a drug injected may cause some discomfort, bruising, minor infection or bleeding. There is also the possibility (although small, because the injection is given by experienced and highly trained clinicians) of damage to structures in the injection area or injection into the wrong area. If any of these things happen, they can be easily treated and will be managed at the time they occur by the project team doctors.

Because participating in the project involves having a dye injected, there is the possibility of an allergic reaction occurring, including anaphylaxis (a very severe and possibly life-threatening allergic reaction). The risk of this happening is very low, but if it did occur all of the needed medication and equipment, as well as doctors trained to treat and manage anaphylaxis, are immediately available in the place you are having the dye injected and scans taken.

This research project involves you as a participant being exposed to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this research project is about 0.6 mSv. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. This risk is believed to be very low.

Because Technetium-99m sulfur colloid gives off a small dose of radiation, it is important that research project participants are not pregnant or breastfeeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and childbearing is a possibility, you will be required to undergo a pregnancy test prior to under-going each scan. It is strongly advised to use effective contraception during the course of your participation in the research project and you can discuss methods of effective contraception with your project doctor. If you do become pregnant whilst participating in the research project, you should advise your project doctor immediately. Your project doctor will withdraw you from the research project and advise on any further medical attention should this be necessary. You must not continue in the research if you become pregnant. If you get pregnant during the project or very shortly after participation in the project the risks to you or the foetus are not significant as the dose of radiation is very small and has not been shown to harm the foetus, even in the very early stages of pregnancy.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features.

What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your project doctor will tell you about it and discuss with you and how it may relate to the research project.

Can I have other treatments during this research project?

Yes. You can have any of your usual treatments or medications during this research project. If you develop any new health issues you should discuss these with the project doctors to ensure that these do not affect your participation in the project.

What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team and they will provide you with a withdrawal of consent form to sign.

If you do withdraw your consent during the research project, the project doctor and relevant project staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the project team up to the time you withdraw will form part of the research project results. If you do not want them to do this, you

must tell them when you withdraw from the research project, and this will be recorded on your withdrawal of consent form.

If you withdraw your consent and participation before completing all six scans of the project, you will not receive the $100 gift voucher.

What happens when the research project ends?

Your participation in the research project ends when you either complete your six scans or when you withdraw your consent. The entire project runs for up to two years. Once all the data is collected from all participants, it will be analysed, and the results will be written up and available to you.

How is the research project being conducted?

What will happen to information about me?

By signing the consent form you consent to the project doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project (including the scan images that are taken during the project) will not be able to identify you and will remain confidential. This data will be stored on a password protected and backed up USB drive dedicated to the project and will be kept for a minimum of 15 years as required by law. After this period of time, it will be destroyed.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided and presented in such a way that you cannot be identified.

Information about your participation in this research project will not be recorded in your health records. Any information obtained for the purpose of this research project will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the project team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you have any complaints regarding this research project or concerns about how it is being conducted, please contact a member of the research team or the HREC at Townsville University Hospital (details at the bottom of this information sheet).

Who is organising and funding the research?

This research project is being conducted by an independent research group made up of clinicians: Dr Adam Holyoak, Dr Mark Little, Dr Tyson Reeve and Dr Theophilus Emeto.

This research project is being funded by a grant from the Emergency Medicine Foundation, and no member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Townsville Hospital and Health Service.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Approval to undertake the research project has been granted by the HREC of the Townsville Hospital and Health Service.

Further information and who to contact:

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal project doctor on 0423852272 or any of the following people:

Clinical contact person

Name	Dr Adam Holyoak
Position	Principal Project Investigator
Telephone	0423852272
Email	Adam.holyoak@health.qld.gov.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Dr Adam Holyoak
Position	Principal Project Investigator
Telephone	0423852272
Email	Adam.holyoak@health.qld.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you

may contact the Chairperson on 07 4433 1440 or email TSV-Ethics-Committee@health.qld.gov.au.