ASP-RBBS Australian Snakebite Project PROCEDURE 05-11-2014 V3

AIM

(1) To investigate whether tiger snake antivenom within 6 hours will prevent myotoxicity in **red-bellied black snake** envenoming

Inclusion Criteria:

- Definite **red-bellied black snake** bite based on expert identification or description of the snake by patient or clinician.
- Presence of early envenoming: systemic symptoms including two of nausea/vomiting, headache, abdominal pain or diarrhoea; elevated aPTT; significant local injury with swelling, bruising and erythema >5 cm diameter

Exclusion Criteria: age < 2 years; bite > 6 hours ago

PROCEDURE

STEP 1 – At any time that blood is taken for routine care (FBC, COAGS, U&E, CK), take **additional research bloods** in a **plain/serum tube** colour varies b/w labs). Note on request forms "**Australian Snakebite Project"**

STEP 2 – Call the ASP investigator on **1800 676 944**. Paperwork can be faxed if this is not already available. The ASP investigator will give you the **STUDY CODE** if the patient meets inclusion criteria and has consented.

STEP 3 – Obtain consent as soon as the patient's condition permits (or from next of kin) and **immediately fax** the **completed Consent Form** and **Datasheet 1** to the fax number below.

STEP 4 - Take the appropriate trial pack from fridge where antivenoms are kept based on the **STUDY CODE**

STEP 5 – Start filling out the **remaining datasheets**; keep with patient notes and continue recording data.

STEP 6 – Give Trial Pack (check the **STUDY CODE** is correct) and record administration time

- The vial is added to 200mL of Normal Saline and given over 20 min via an infusion pump.

STEP 7 -

Do research bloods (serum) just prior to study vial administration.

AND

At **6 hours** post-bite take	Routine + Research bloods
At **12 hours** post-bite take	Routine + Research bloods
At **18 hours** post-bite take	Routine + Research bloods
At **24 hours** post-bite take:	Routine + Research bloods
Then every 12 hours until discharge	Routine + Research bloods

STEP 8 –If a reaction to the treatment occurs, call the National Study Line and take additional samples as outlined on the adverse reaction datasheet.

STEP 9 – Patients should be observed for 24 hours post-bite unless the CK is increasing. If the CK is rising they should then be kept until the CK is decreasing and may need ongoing treatment for myotoxicity.

STEP 10 – Fax all completed datasheets 1-4 and medication chart to the fax number below

STEP 11 – Please call us on one of the phone numbers below just prior to discharge so that we can make appropriate follow-up arrangements with the patient

National Study Line (24 hrs): 1800 676 944 (IF THIS FAILS contact Dr Geoff Isbister **0438 466 471)**

FAX NUMBER FOR SUBMITTING CONSENT FORMS AND DATASHEETS: (02) 49110501

ASP Australian Snakebite Project Datasheet 1

Including ASP- RBBS

STUDY ID NUMBER:

DOCTORS NAME

Patient contact telephone number(s)

HOSPITAL:

Patient Name and URN:

or Patient Sticker Label

Arrival Date: dd / mmm / yyyy Arrival Time: : 24 hour clock

Pt. SEX: M / F

Date of Birth: dd / mmm / yyyy

PREVIOUS HOSPITAL (If transferred):

HISTORY OF BITE AND FIRST AID

Bite Date: dd / mmm / yyyy Time: : **24 hour clock** Part of body bitten:

Snake clearly seen to bite? ☐Yes ☐No Nearest suburb/town/landmark:

Circumstances of bite (activity at the time): Number of bites:

Symptoms/signs so far: SEE NEXT PAGE (Clinical Datasheet 2) Time of symptom onset: : **24 hour clock**

Has the patient been immobilised (kept on a stretcher/not walking) since the bite? ☐Yes ☐No

Has a PRESSURE BANDAGE +/- SPLINT been applied prior to arrival at this hospital? ☐Yes ☐No

If **Yes:** Who was it first applied by? Text Time first applied: : **24 hour clock**

Was it further reinforced (improved) by a health professional BEFORE arrival at this hospital? ☐Yes ☐No Time reinforced: :

Was it removed BEFORE arrival at this hospital? ☐Yes ☐No Time removed? :

INITIAL ASSESSMENT & ACTIONS

Was a pressure bandage in place PRIOR TO arrival? ☐Yes ☐No

Characteristics:
- ☐ **Loose** &/or one layer only &/or part of limb only
- ☐ **Firm**, 2 or more layers, whole limb, well appplied
- ☐ Acting as a venous torniquet- limb swollen
- ☐ Acting as an arterial torniquet- limb ischaemic

Was the bitten limb splinted PRIOR TO arrival? ☐Yes ☐No

Splinted with:

Was pressure-immobilisation/splinting applied or improved on or after arrival in this hospital? ☐Yes ☐No

VDK / SNAKE ID (If available/performed)

Cut window over suspected bite site - are TEETH/FANG MARKS clearly seen? ☐Yes ☐No How many?

VENOM DETECTION KIT (VDK) tests performed by: ☐LAB (Preferred) ☐ED Doctor

VDK Result **BITE SITE:**

VDK Result **URINE** (Only required if bite site VDK is negative **and** Pt. is envenomed):

SNAKE, if available, sent for identification? ☐Yes ☐No If Yes, to whom:

ID result:

FAX THIS PAGE IMMEDIATELY with COMPLETED CONSENT FORM (02)4911 0501

Data Sheet 2

Red Bellied Black Snake Study

OBSERVATIONS and TREATMENTS

Hospital sticker

STUDY Code = ☐ (supplied by on-call investigator)

Time Point	Admission	Pre-A/V	Post-Bite 6 hours	Post-Bite 12 hours	Post-Bite 18 hours	Post-Bite 24 hours
Actual Time (hrs)	____:____	____:____	____:____	____:____	____:____	____:____
Pain	☐	☐	☐	☐	☐	☐
Swelling	☐	☐	☐	☐	☐	☐
Bruising	☐	☐	☐	☐	☐	☐
Tender Lymph Node	☐	☐	☐	☐	☐	☐
Headache	☐	☐	☐	☐	☐	☐
Nausea	☐	☐	☐	☐	☐	☐
Vomiting	☐	☐	☐	☐	☐	☐
Abdo Pain	☐	☐	☐	☐	☐	☐
Diarrhoea	☐	☐	☐	☐	☐	☐
Sweaty	☐	☐	☐	☐	☐	☐
Myalgia (Please circle one)	Nil Local Generalised	Nil Local Generalised	Nil Local Generalised	Nil Local Generalised	Nil Local Generalised	Nil Local Generalised
Muscle Pain (Please circle one)	Nil Local Generalised	Nil Local Generalised	Nil Local Generalised	Nil Local Generalised	Nil Local Generalised	Nil Local Generalised
Change in Smell	☐	☐	☐	☐	☐	☐
Anti-emetic given	☐	☐	☐	☐	☐	☐

MANAGEMENT & BLOOD SAMPLING

STUDY ID NUMBER:

REMOVAL OF PRESSURE-IMMOBILISATION

DATE: TIME: : 24 hour clock PATIENT WEIGHT kg

PREMEDICATIONS (PRIOR TO FIRST DOSE OF ANTIVENOM), IF ANY

MEDICATION	DOSE and ROUTE	TIME	ANY ADVERSE EFFECT?
		:	Yes / No
		:	Yes / No
		:	Yes / No

If YES go to Datasheet 4

ANTIVENOM

TYPE	BATCH NUMBER(S)	No. of vials	Time STARTED	DURATION (Minutes)	ANY ADVERSE EFFECT?
			:		Yes / No
			:		Yes / No
			:		Yes / No
			:		Yes / No

If YES go to Datasheet 4

CLOTTING FACTOR REPLACEMENT (FFP, CRYO etc.)

TYPE	Amount	Time STARTED	DURATION (Minutes)	ANY ADVERSE EFFECT?
		:		Yes / No
		:		Yes / No
		:		Yes / No
		:		Yes / No

If YES go to Datasheet 4

PLEASE RECORD BLOOD SAMPLING TIMES

IMPORTANT NOTE: All cases with coagulopathy must have research bloods at 3 hours post antivenom and a full set of both research bloods and coagulation studies at 6 hours post first dose of antivenom.

DATE	TIMES (24 hour clock)						
	:	:	:	:	:	:	:
	:	:	:	:	:	:	:
	:	:	:	:	:	:	:

LABORATORY RESULTS: **Please attach copies of all investigation results reported by your hospital laboratory.**

ADVERSE REACTION

STUDY ID NUMBER:

(You may submit multiple copies if more than one reaction occurs;
either photocopy this datasheet or contact the National Study Line to arrange for another to be faxed)

DATE & TIME OF ONSET dd / mmm / yyyy : 24 hour clock

LIKELY CAUSE

REACTION FEATURES:

Erythema/ Urticaria	Angioedema	Nausea	Vomiting	Abdo/Pelvic Pain	Throat tightness	Chest tightness	Cough
Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

Stridor	Dyspnoea	Wheeze	Accessory Muscle Use	Intercostal indrawing	Hypoxaemia (SpO2<=92%)	Altered consciousness	Diaphoresis
Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

BP Baseline BEFORE Rn	BP LOWEST during Rn	BP HIGHEST during Rn
/	/	/

OTHER:

EMERGENCY TREATMENT

If space here is insufficient please photocopy and attach drug and fluid administration records

INTERVENTION	DOSE and ROUTE (IF DRUG/FLUID)	TIME
		:
		:
		:
		:

ONCE EMERGENCY TREATMENT HAS BEEN STARTED PLEASE ALSO DO THE FOLLOWING:

1. TAKE ADDITIONAL RESEARCH BLOODS (1xSerum, 1xCitrate) PLUS 1xEDTA (Purple) TUBE and send to the laboratoiry immediately (ON ICE if available)

(i) 10-15 minutes after reaction onset/emergency treatment — Yes / No — TIME TAKEN: :

(i) One hour after reaction onset/emergency treatment — Yes / No — TIME TAKEN: :

2. CONTACT THE ASP-FFP INVESTIGATOR to discuss case management and investigation, and to arrange for another Datasheet 4 to be faxed if required.

DATE & TIME OF RESOLUTION OF THE REACTION

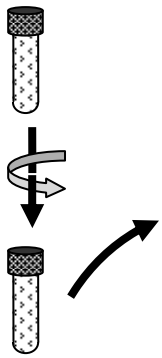
dd / mmm / yyyy : 24 hour clock

NOTES/ COMMENTS:

Australian Snakebite Project (ASP-RBBS)
LABORATORY PROTOCOL

1. Serum

Blood in plain or serum-separator (SST) tube



2000g for 10 min (3800-4000 rpm in a standard bench top centrifuge)

1.6-2mL aliquots of serum (in 2mL screw cap cryotubes if available)

Label each tube with **sample type** ("**Ser**"), **patient ID**, **date & time of collection**.

Keep samples from each collection time separate in a single specimen bag, along with a copy of the corresponding request form.

Freeze as soon as possible and transport in dry ice (or other suitable frozen transport) to -80°C storage. **NOTE: please freeze all available (earlier) left-over samples, even if they have been left unfrozen for several days, noting the date and time of freezing on the request forms.**

From **EDTA samples** please prepare a **blood film** to send to us, which we use to measure red cell fragmentation – an **unstained** film is preferable.

2. Left-over serum/plasma from earlier time points

The most important samples are the first ones taken, when the patient and doctor may not be aware of the study. Even if these samples have not been processed according to the procedures above, we can obtain important information from them. Therefore, please ensure that no snakebite samples are discarded without first discussing with a study coordinator (contact details at the bottom of this page).

3. If a serious adverse reaction occurs- EDTA plasma as well

If an allergic reaction occurs, the doctors may send additional samples of serum, plasma (citrate) and plasma (EDTA) to assess anaphylactic mediators, 15 minutes and 60 minutes after reaction onset. Please process as per 1 & 2 and freeze immediately. EDTA plasma needs a single spin only, and can be frozen in aliquots of 1.6-2 ml.

4. Results from your lab

If time permits we would appreciate copies of all results (biochemistry, haematology and coagulation):

WA: Centre for Clinical Research in Emergency Medicine (CCREM),Dept. of Emergency Medicine, Royal Perth Hospital, GPO Box X2213, Perth, WA 6000

Other States: Attn: Geoff Isbister , Dept. of Clinical Toxicology & Pharmacology, Calvary Mater Newcastle Hospital, Edith St, Waratah, NSW 2298

OR FAX from all States: (02) 4911 0501

National Study Line (24 hours): 1800 676 944. IF THIS FAILS then contact a Chief Investigator directly: Dr Geoff Isbister **0438 466471** or A/Prof Simon Brown **0419 796678**
Fax number for sending laboratory results: (02) 4911 0501

5. Sample transport

Serum & Plasma samples (send in a single batch on patient discharge)

NSW and VIC	TAS	SA
For Dr Geoff Isbister Specimen Reception, Hunter Area Pathology Service, John Hunter Hospital, Lookout Road, New Lambton Heights, NSW 2305 *PLACE IMMEDIATELY IN -20 FREEZER*	Keep in -80. Contact Jenny Gudden on 62227599 or A/Prof Simon Brown on 0419796678 to arrange transfer to Jack Jumper Allergy Program Laboratory, Royal Hobart Hospital.	c/- Vaughan Williams, Coagulation & Haematology Laboratory, Women's & Children's Hospital 72 King William Road, North Adelaide, SA 5006 *PLACE IMMEDIATELY IN -20 FREEZER*

QLD	NT	WA
Haematology Supervisor Pathology Central Spec. Reception Block 7 Level 3, Royal Brisbane & Women's Hospital, Butterfield Street, Herston, QLD 4029. P. (07) 3646 5233 NOTE TO RECEPTION STAFF: Forward direct to Coag/Special Investigations *DO NOT UNPACK*	c/- Bart Currie Menzies School of Health Research Rocklands Drive Casuarina, NT 0811 *PLACE IMMEDIATELY IN -20 FREEZER*	Nick Michalopoulos Haematology, Pathwest J Block, QE II Medical Centre, Nedlands, WA 6009 *PLACE IMMEDIATELY IN -20 FREEZER*

Background information about this study

ASP-RBBS aims to: 1. To investigate whether early antivenom administration in RBBS envenoming will prevent myotoxicity, reverse non-specific effects of envenoming (i.e. nausea, vomiting, abdominal pain, diarrhoea) and prevent local effects.
2. To determine the frequency of allergic reactions, including anaphylaxis, after the administration of early antivenom in RBBS envenoming.

Australian Snakebite Project (ASP)
A collaboration of Australian country, regional and teaching hospitals

Participant Information and Consent Form

Full Project Title: A randomised controlled trial of antivenom for red-bellied black snake envenoming

Principal Researchers: A/Prof Geoff Isbister, Prof Nick Buckley

_____

This Participant Information and Consent Form are **5** pages long. Please make sure you have all the pages.

1. Your Consent

You are invited to take part in the *Australian Snakebite Project and Red-bellied black snake Study*. Please read this information carefully and feel free to ask any questions.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in this research.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. Purpose and Background

The purpose of this project is to investigate the effectiveness and safety of antivenom for the treatment of red-bellied black snake bites/envenoming

Red-bellied black snakes are one of the commonest snakes to cause snakebites and envenoming in Eastern Australia. Most bites by the red-bellied black snake will cause the person to feel unwell, with nausea, headache, abdominal pain and vomiting. In most cases the person will get better without any specific treatment. However, in a small number of bites, between 1 in 20 and 1 in 10 bites, the person will develop toxic injury to the muscle which can lead to muscle pain and weakness that takes days to resolve, and in some cases may cause kidney damage. Other effects include the development of an ulcer at the bite site and occasionally the loss of smell.

Antivenom is the major treatment for most snake bites and is a mixture of antibodies that neutralise the snake toxins – like an antidote. Red-bellied black snake bites are not routinely treated with antivenom because they appear to cause minor effects and there is concern about the risk of allergic reactions to antivenom. However, recent work by the investigators suggests that the early use of antivenom will reduce the chance of people developing muscle damage. The reason for this is that antivenom neutralises the effect of the venom toxins and prevents the venoms from damaging the muscles. It is therefore important to determine if giving antivenom soon after the bite (within 6 hours) will reduce the chance of muscle damage which has never been done before. Tiger snake antivenom is the one recommended for red-bellied black snake envenoming.

This study will determine whether antivenom will reduce the chance of muscle injury in red-bellied black snake bites.

This study is being funded by the National Health and Medical Research Council of Australia.

3. Procedures

All participants: If you take part in this project you will receive standard care, and any other necessary treatments including pain relief, intravenous fluids and medicine to treat nausea and vomiting. We will record information about your snakebite and laboratory tests that are

performed. In addition we will take a small additional amount of blood from you at the same time that bloods are taken for routine laboratory tests and therefore will not cause you any additional discomfort or inconvenience. We will use this extra blood to measure the amounts of venom and antivenom in your blood.

In addition to other standard treatments you will be randomly (like tossing a coin) put into one of two groups. The first group will receive intravenous tiger snake antivenom. The second group will receive intravenous 50% glucose solution (placebo). Antivenom or 50% glucose will be given into the vein (intravenously) according to the normal hospital protocol.

Neither you, the treating doctor nor the investigators will know which group you are put into or whether you received antivenom or placebo.

Blood will be taken as outlined in paragraph one of this section. You will be involved in the study for the duration of your stay in hospital which will usually be for a period of 24 to 48 hours. Occasionally because of severe complications of the snake bite your hospital stay may be longer. If you have any complications we will record information about these complications and may request additional blood samples to help us determine the nature of these complications.

We will also contact you 7 to 10 days after you have been discharged from hospital to determine if you have developed any delayed effects from the use of antivenom.

4. Collection of Tissue Samples for Research Purposes

By consenting to take part in this study, you also consent to the collection, storage and use of blood samples as described above. These tests will be done within 3 years of blood collection. The remaining blood will be kept for 15 years and may be used for associated research on allergic reactions, blood abnormalities from snake bite and other markers of snake venom activity when these tests become available or are developed. All samples will be destroyed after 15 years.

5. Possible Benefits

We cannot guarantee that you will receive any benefits from this project except that your treatment will be guided by national experts on snake bite. However, your involvement in the study will benefit people who suffer red-bellied black snake bite in the future or any snake bite that can cause muscle damage.

6. Possible Risks

Important risks for you being part of the study include side-effects to antivenom, however antivenom is administered to hundreds of patients each year with most reactions being allergic and usually mild. On occasion these reactions can be severe requiring treatment with adrenaline. About 1 in 4 people will develop a rash or itchiness following the administration of antivenom. About 1 in 20 people will have a more severe allergic reaction or anaphylaxis which results in a low blood pressure.

7. Injury

In the event that you suffer an injury as a result of participating in this research, hospital care and treatment will be provided by the public health service at no extra cost to you.

8. Privacy, Confidentiality and Disclosure of Information

All records dealing with your participation in this study will be kept under safe storage for 15 years after completion in locked offices and buildings of the investigators. Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project to ensure accurate data linkage between clinical results and laboratory reports.

Data stored on computer will be de-identified (your name will be not be stored in the database) and password protected. Individual participants in the study will not be identifiable in any reports of the data from the protocol or any publications resulting from the research.

Where study staff identify missing data required for purposes of this research a request will be made to the treating hospital/s for copies of relevant clinical information held in the participants' medical record.

9. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged 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 wish to withdraw your blood samples from the study these will be destroyed by the investigators as well as any information collected.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, or your relationship with those treating you.

10.Ethical Guidelines and Approvals

This project (Reference number: 10/12/15/3.04) will be carried out according to the *National Statement on Ethical Conduct in Research Involving Humans* (March 2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Human Research Ethics Committees of Hunter New England Area Health Service as the lead committee for NSW and QLD investigation sites. Ethics approval has been obtained at all other sites involved but overall responsibility is with the Hunter New England Area Health Service.

11.Further Information, Problems

If you require further information or if you have any problems concerning this project (for example, any side effects), please contact the principal researchers. The researcher responsible for this project is **Dr Geoff Isbister** (Mobile: 0438 466471 24hrs/day).

12.Complaints or Concerns

If you have any complaints or concerns about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact the Hunter New England Health Human Research and Ethics Committee (HREC) as below:

Hunter New England Region
Dr Nicole Gerrand
Manager, Research Ethics and Governance, Hunter New England Local Health Network
Telephone: 02 4921 4950
Email: hnehrec@hnehealth.nsw.gov.au

PATIENTS COPY

Australian Snakebite Project (ASP)
A collaboration of Australian country, regional and teaching hospitals

NSW GOVERNMENT Health
Hunter New England Local Health District

Queensland Government
Queensland Health

Consent Form
Full Project Title: A randomised controlled trial of antivenom for red-bellied black snake envenoming

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I have read and I understand the Participant Information **version** *7* dated ***11Jan 2016***.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this project according to the conditions in the Participant Information.

I understand that I will be given a copy of the Participant Information and Consent Form to keep.

I understand that the researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

I understand that there may be occasion for the research staff to request copies of information from my medical record that will allow the completion of the study datasheets and associated information for the study. Specifically I consent to the hospital providing the details of this admission after the event when they are contacted by the research staff.

I consent to being randomised and understand I may or may not receive antivenom.*)*

Participant's Name (printed) ……

* Signature …… Date

Witness Name (printed) ……

* Signature …… Date

☐ I consent to the storage of any additional blood for further snake bite research projects.

Name of Person giving Consent (printed) ……

* Signature …… Date

Note: **All parties signing the Consent Form must date their own signature.**

Consent Form

Full Project Title: A randomised controlled trial of antivenom for red-bellied black snake envenoming

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Australian Snakebite Project (ASP)
A collaboration of Australian country, regional and teaching hospitals

NSW GOVERNMENT Health
Hunter New England Local Health District

Third Party Consent Form *(TO BE USED BY PARENTS/GUARDIANS OF CHILDREN.)*
Full Project Title: A randomised controlled trial of antivenom for red-bellied black snake envenoming

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I consent to _____ being randomised and understand they may or may not receive antivenom.

Participant's Name (printed) ……

Name of Person giving Consent (printed) ……

Relationship to Participant: ……..

* Signature …….. Date

Witness Name (printed) ……..

* Signature ……. Date

☐ I consent to the storage of any additional blood for further snake bite research projects.

Name of Person giving Consent (printed) ……

Relationship to Participant: ……..

* Signature …… Date

***Note:* All parties signing the Consent Form must date their own signature**

Australian Snakebite Project (ASP)
A collaboration of Australian country, regional and teaching hospitals

Third Party Consent Form *(TO BE USED BY PARENTS/GUARDIANS OF CHILDREN.)*

Full Project Title: A randomised controlled trial of antivenom for red-bellied black snake envenoming

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