VENOM IMMUNOTHERAPY - SCH

DRUG PROTOCOL©

DOCUMENT SUMMARY/KEY POINTS

- Venom Immunotherapy is recommended in children at risk of anaphylaxis from bee or wasp sting.
- Standard, Rush and Modified Rush protocols may be considered, patients undergoing rush protocols require hospitalisation for approximately 5 days.
- The Medical Officer must inform Pharmacy Technology Unit 1 week prior to admission to enable sufficient time for ordering and preparing the products.
- All doses must be prescribed on the national medication chart and administered by a nurse performing the necessary observations.

CHANGE SUMMARY

- Replaces SCH.C.20.17 Administration of Venom Immunotherapy

READ ACKNOWLEDGEMENT

- Medical, Nursing and Pharmacy staff involved in the prescription, manufacturing and administration of Venom Immunotherapy at SCH should read and acknowledge this document.

Note: Separate Practice Guidelines may be required to cover all aspects of management.

Approved by:	SCHN Policy, Procedure and Guideline Committee	SCH Medicines Advisory Group
Date Effective:	1st June 2013	**Review Period**: 3 years
Team Leader:	Head of Department	**Area/Dept**: SCH Immunology

Introduction / Background

Venom Immunotherapy (VIT) is recommended for all children who experience sting induced anaphylaxis.[1] It reduces the risk of anaphylaxis from around 60% to 5% for these patients with a prolonged benefit observed 10-15 years after the cessation of treatment.[1]

The procedure involves administering incremental doses of venom according to standard protocols. The protocols may be modified for individual patients but the basic principle of incremental dosing remains constant. Standard, Rush and Modified Rush protocols are available and have been found to be safe and effective in children.[2]

Approved Indications

- Desensitisation of patients with bee or wasp sting allergic patients at risk of anaphylaxis from a sting.

Precautions

- Patient with poorly controlled asthma, acute infection
- Due to the possibility of anaphylaxis it is recommended that adrenaline and hydrocortisone are available in a kidney dish in the locked drug room should they be required and prescribed on the medication chart as a precautionary measure:
  - **Adrenaline 1:1000 injection (1mg/mL)** (Dose: 0.01mL/kg IM to a maximum recommended dose of 0.3mL)
  - **Hydrocortisone 100mg injection** (Dose: 2mg/kg to a maximum of 100mg IV)

Presentation, Stability and Storage[3]

Prepared solutions have varying expiration depending on the reconstituting fluid used and product concentration. Expiration dates are listed in Table 1 and apply only to medications stored in the refrigerator between 2 and 8 degrees C.

Table 1: Recommended expiration dates following reconstitution with albumin- saline

Venom Concentration	Recommended Expiry Date
100microg/mL	6 months
10microg/mL	30 days
1microg/mL	30 days
0.1microg/mL	14 days
Less than 0.1microg/mL	Prepare fresh daily

A reconstituted vial containing 6mL of 100 microg/mL venom extract has a 6 month shelf life and is designed to be used in a multi dose fashion for individual patients. Where multidose vials are stored in the clinic they must ***only*** be used to multidose for the ***one individual patient*** over the 6 month period. No other patient should be dosed from this vial.

Dose

Standard VIT protocol is displayed below in Table 2. The listed doses are given at weekly intervals by subcutaneous injection into the deltoid region or thigh.[3,4] This is usually done as an outpatient and does not require a hospital admission.

Table 2

Dose Number	Concentration (microg/mL)	Volume (mL)	Dose Number	Concentration (microg/mL)	Volume (mL)	Dose Number	Concentration (microg/mL)	Volume (mL)
1	1	0.05	5	10	0.05	9	100	0.05
2	1	0.1	6	10	0.1	10	100	0.1
3	1	0.2	7	10	0.2	11	100	0.2
4	1	0.4	8	10	0.4	12	100	0.4
						13	100	0.6
						14	100	0.8
						15	100	1

Rush VIT protocol

Patients admitted to SCH will usually undergo Rush VIT protocols. Table 3 shows a **Rush VIT protocol**.[3] The listed doses are given *at 2 hourly intervals or as specified by Medical Officers* by subcutaneous injection into the deltoid or thigh region.

Treatment usually commences at column 1 and proceeds downwards until the patient can proceed to the next column receiving the next concentration until all doses are completed or the treatment ceased.

Table 3

1. Concentration 0.0001 microg/mL	**2.** Concentration 0.001 microg/mL	**3.** Concentration 0.01 microg/mL	**4.** Concentration 0.1 microg/mL	**5.** Concentration 1 microg/mL	**6.** Concentration 10 microg/mL	**7.** Concentration 100 microg/mL
0.1mL	0.1mL	0.1mL	0.1mL	0.1mL	0.1mL	0.1mL
0.2mL	0.2mL	0.2mL	0.2mL	0.2mL	0.2mL	0.2mL
0.4mL	0.4mL	0.4mL	0.4mL	0.4mL	0.4mL	0.4mL
0.8mL	0.8mL	0.8mL	0.8mL	0.8mL	0.8mL	0.5mL
						0.6mL
						0.8mL
						0.9mL
						1mL

The patient is admitted to hospital for the duration of the treatment. The end result of both protocols is to achieve a maintenance dose of 1mL of 100microg/mL venom extract.

Duration of treatment

The usual duration of stay in hospital using a Rush VIT protocol is 5 days.[1] Once the patient has achieved a maintenance dose the treatment will continue with subcutaneous injection on a monthly basis for the next 3 to 5 years as an outpatient.[1,4]

Administration

- All doses of VIT, including test doses and any other drugs e.g. adrenaline to be ordered on medication chart by the Immunology team based on the above protocol.
- VIT to be administered by Registered Nurses as per the medication chart.
- Syringes to be labelled sequentially by the PTU. Each dose should be administered as ordered. Relevant SCH Clinical Policies to be followed: 5.06 Administration of Subcutaneous Medications.
- Sequential doses are to be given subcutaneously as per the medication chart or as instructed by Immunology Team.
- Only the pre-prepared, single dose syringes supplied by PTU are to be used (**no mixing or diluting of the venom should occur on the ward**).
- Sequential doses should be injected in a rotating fashion in the deltoid region of both arms and/or both thighs.
- Each injection site should be marked by circling them. This is done to determine if any local reaction has occurred and to which dose.
- Doses should be administered every 2 hours unless otherwise ordered by the Immunology Team until the VIT is completed or an adverse event occurs.

Safety and Patient Monitoring

Routine observations

- The child is to have a baseline set of Observations done prior to commencing the VIT including: Weight, Temperature (T), Pulse (P), Respiratory rate (RR), Blood pressure (BP), Oxygen Saturations (Sa02), Chest auscultation and observation for signs of rashes or hives on skin. Relevant Sydney Children's Hospital Clinical policy that is to be followed, (SCH.C.10.P.1 Pulse Oximetry Guidelines).
- P, BP, RR, $Sa0_2$ and chest auscultation should be performed by the RN 30 minutes **after** each dose or if any adverse event occurs. The frequency of these observations is to be determined by the nurse and medical officer caring for the child.

Adverse Events[3]

- **Small local reaction** (swelling or redness less than 5cm diameter around the injection site).
  - Continue prescribed protocol

- **Large local reaction** (swelling or redness greater than 5cm diameter around the injection site).
  - Continue prescribed protocol and Page Immunology Registrar or ward Registrar to review patient.
- **Systemic Reaction** (Generalised urticaria or rash; lip, tongue or eyelid swelling; vomiting; stridor; wheeze; continuous coughing etc)
  - Withhold the next dose, stay with patient and monitor closely. Page Immunology Registrar or Ward Registrar immediately to come and assess patient.
- **If symptoms worsen**
  - Continue to monitor patient closely
  - Page Immunology Registrar or Ward Registrar again and explain urgency of situation.
  - Give medication as prescribed (e.g. oral antihistamine, inhaled salbutamol, IM adrenaline) if instructed by the Medical officer or if unable to immediately contact the Medical officer)
  - If Respiratory or Cardiovascular Arrest is assessed to be imminent
  - Call 2222 and begin normal resuscitation procedures
    Call 2222 if no response from Immunology Registrar or Ward Registrar following administration of IM adrenaline.

References

1. M. T. Krishna, P. W. Ewan, L. Diwakar, S. R. Durham, A. J. Frew, S. C. Leech and S. M. Nasser, Diagnosis and management of hymenoptera venom allergy: British Societyfor Allergy and Clinical Immunology (BSACI) guidelines Clinical & Experimental Allergy, 41, 1201–1220
2. F. Bonifazi, M. Jutel, B. M. Bil,J. Birnbaum, U. Muller and the EAACI Interest Group on Insect Venom Hypersensitivity Prevention and treatment of hymenoptera venom allergy: guidelines for clinical practice Allergy 2005: 60: 1459–1470
3. Product Information, Albey venom, EBOS Group Pty Ltd. Kingsgrove NSW. Last updated March 2011
4. Stinging insect hypersensitivity: A practice parameter update 2011 Joint Task Force on Practice Parameters, representing the American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and the Joint Council of Allergy, Asthma and Immunology. (editors) David B. K. Golden, MD, John Moffitt, MD, and Richard A. Nicklas, MD J Allergy Clin Immunol 2011;127:852-4.