

## CROUP ORAL STEROID STUDY: GUIDANCE FOR DOCTORS

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It is hoped that this information will be of help in decision-making, and to standardise care of patients, but strict adherence to these guidelines is not necessary for the purposes of the study. Clinical judgement should be exercised; if in doubt, ask a senior colleague for help.

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### DIAGNOSIS OF CROUP

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Based on features of a hoarse voice or a barking cough and stridor, with or without increased work of breathing (as evidenced by chest-wall retractions). This could be directly observed, or elicited in the history. The child may have the typical brassy 'sea-lion' cough, and this is adequate to diagnose croup without stridor or recessions being evident.

Asthma or bronchiolitis with manifestations of lower airway obstruction occasionally co-exist with croup in the same patient, due to the common viral aetiology. If unsure, one clinical manoeuvre to distinguish wheeze from stridor is to move the stethoscope progressively closer to the larynx – stridor will become louder. Generally, wheeze is expiratory whereas stridor inspiratory in timing, but this is not a reliable feature. If the clinical picture is predominantly asthma or bronchiolitis more than croup, the child should not be included in the study as croup must be the main diagnosis.

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### CRITERIA FOR ORAL STEROID

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These are not clear in the literature at present. Some institutions only use oral steroids when stridor is present; however, the tendency over the last 5-10 years has been towards more liberal use of steroids, since lower doses have been recognised to be equally effective.

All patients enrolled in this study will receive oral steroid, even those with mild croup who are discharged home.

Side effects from a single dose of dexamethasone or prednisolone are likely to be extremely rare, as demonstrated by previous studies.(4,9)

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### CRITERIA FOR NEBULISED ADRENALINE (EPINEPHRINE)

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Nebulised adrenaline is an effective short-term treatment for moderate and severe croup, and probably works by causing upper airway vasoconstriction and decreasing mucosal oedema.

Indications are not clearly established in the literature, but most clinicians would use nebulised adrenaline for children with:

Progressively worsening clinical condition (increasing croup score)

Severe croup from the outset (severe retractions)

Hypoxaemia (SaO<sub>2</sub> less than 92%)

As a temporary measure prior to intubation

**Essentially, children should be treated in the routine fashion and be given nebulised adrenaline according to the usual practice of the department.**

Dose: depends on the type of adrenaline used

1 1:1000 L-adrenaline ampoules (1mg in 1 ml) (normal 'crash-cart' adrenaline vials)

2 Give 0.5mL/kg to max of 5mL

3 made up to total volume of 4ml with normal saline

4  
5  
6 or alternatively

7  
8 1% adrenaline solution

9 give 0.05mL/kg to max of 1.5mL, diluted to total 4mL with normal saline

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11  
12 All children who have required a single dose of nebulised adrenaline should be observed for at  
13 least three hours. Those who have improved, having received steroids, may be discharged home.

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### 14 CRITERIA FOR ENDOTRACHEAL INTUBATION

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17 This is seldom required in children who have been given steroids and is a clinical decision to be  
18 made by an experienced emergency physician, paediatrician, anaesthetist or intensivist. Consider  
19 in the child with:

20 Exhaustion despite nebulised adrenaline (epinephrine)

21 Severe retractions despite nebulised adrenaline (epinephrine)

22 Intubation should only be performed by the most experienced operator available, preferably a  
23 paediatric anaesthetist, where available.

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### 24 CRITERIA FOR ADMISSION TO HOSPITAL

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27 The decision to admit a child should be based on the normal practice and policy of the Emergency  
28 Department.

29 One possible approach would be to admit all children who:

30 Have stridor at rest, audible without a stethoscope, 2 hours after oral steroid

31 Have received nebulised adrenaline and not clearly improved

32 Need admission for other reasons, e.g. remote from hospital / social reasons

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### 33 LEAVING THE EMERGENCY DEPARTMENT FOR ADMISSION TO THE WARD

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36 Determining whether a child is 'stable' to go to the ward is once again a clinical decision and will  
37 depend on local arrangements. Generally, transfer to the ward would be considered safe when:

38 Croup score 0-3

39 No indication for nebulised adrenaline (i.e., condition not deteriorating)

40 Ward ready and resourced to care for child

41  
42  
43 Under some circumstances it may be necessary for a doctor to accompany child to the ward.

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### 44 DISCHARGE FROM THE EMERGENCY DEPARTMENT

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47 Doctors with the appropriate experience could allow a child to go home, typically when:

48 Croup score 0 or 1

49 No stridor at rest audible (without stethoscope)

1 Steroid has been administered  
2 Family and social factors allow  
3

4 Parents should be advised to return to hospital if the child develops persisting stridor at rest.  
5 Stridor may recur when the child is upset, but should not persist once the child calms down.  
6  
7

8 Although data will be collected for up to 12 hours in this study, the child should not be kept in  
9 hospital merely for the purposes of the study. Children should be discharged when clinically  
10 appropriate, as this will provide the most realistic and useful information for the study.  
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## DATA COLLECTION SHEET

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### Croup Oral Steroid Study: DATA COLLECTION SHEET

Consent Signed: YES  NO

If NO then reason: \_\_\_\_\_

Study centre: JHC PMH Other: \_\_\_\_\_

Child's Date of birth (dd/mm/yyyy): \_\_\_\_\_ Child's Initials: \_\_\_\_\_

Child's Gender M / F

Child's Weight: \_\_\_\_\_ kg

Contact Phone no: Home: \_\_\_\_\_ Mobile: \_\_\_\_\_

Inclusion criteria (please tick):

Age over 6 months of age YES  NO

Clinical diagnosis of croup YES  NO

Parents contactable by telephone YES  NO

Parents speak English YES  NO

Weight: no more than 20kg YES  NO

Exclusion criteria (please tick):

Is there a high clinical suspicion of an alternative diagnosis?:

Bacterial tracheitis: YES  NO

Epiglottitis: YES  NO

Retropharyngeal abscess: YES  NO

Inhaled foreign body: YES  NO

Other (angioedema, vascular ring, subglottic stenosis) YES  NO

Known allergy to prednisolone or dexamethasone YES  NO

1 Immunosuppressive disease or treatment YES  NO

2 Steroid therapy in past 14 days YES  NO

3 Enrolled in this study in past 14 days YES  NO

4 Date of randomisation (today's date) (dd/mm/yyyy): \_\_\_\_\_

5 Bottle number (4 digits): \_\_\_\_\_

6 Triage time: \_\_\_\_\_

7 Initial Croup score at time zero (0-17): \_\_\_\_\_

8 Time of administration of trial drug (hh:mm): \_\_\_\_\_

### Westley Croup Score

<b>Inspiratory stridor</b>	None	0	<b>Cyanosis</b>	None	0
	At rest with stethoscope	1		With agitation	4
	At rest without stethoscope	2		At rest	5
<b>Retractions</b>	None	0	<b>Level of consciousness</b>	Normal (including sleep)	0
	Mild	1		Disoriented	5
	Moderate	2			
	Severe	3			
<b>Air entry</b>	Normal	0			
	Decreased	1			
	Severely decreased	2			

		Initial	1hr	2hr	3hr	4hr	5hr	6hr	12hr
<b>Inspiratory stridor</b>	0								
	1								
	2								
<b>Retractions</b>	0								
	1								
	2								
	3								
	4								
<b>Air Entry</b>	0								
	1								
	2								
<b>Cyanosis</b>	0								
	4								
	5								
<b>Level of consciousness</b>	0								
	5								

Was nebulised adrenaline (epinephrine) required? YES  NO

Time of adrenaline (hh:mm): \_\_\_\_\_

Further adrenaline doses at (hh:mm): \_\_\_\_\_

Was endotracheal intubation required? YES  NO

Time of intubation (hh:mm): \_\_\_\_\_

Vomited within 30 minutes of 1<sup>st</sup> dose: YES  NO

Vomited within 30 minutes of 2<sup>nd</sup> dose: YES  NO

If child vomits second dose then remove from trial and treat as per hospital protocol

Please list (and describe) any other adverse clinical events:

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1 \_\_\_\_\_  
 2 \_\_\_\_\_  
 3 \_\_\_\_\_  
 4 Were any of these adverse events thought to be due to the administration of the trial steroid?  
 5 Please elaborate:  
 6 \_\_\_\_\_  
 7 \_\_\_\_\_  
 8 \_\_\_\_\_  
 9 \_\_\_\_\_  
 10 \_\_\_\_\_  
 11 \_\_\_\_\_

12 Number of additional doses of steroid given, other than trial drug: \_\_\_\_\_  
 13 \_\_\_\_\_  
 14 \_\_\_\_\_  
 15 \_\_\_\_\_

16 Time ready for transfer to ward or ED Obs Ward (hh:mm): \_\_\_\_\_  
 17 \_\_\_\_\_

18 Time of transfer to ward or ED Obs Ward (hh:mm): \_\_\_\_\_  
 19 \_\_\_\_\_  
 20 \_\_\_\_\_  
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22 Time ready for discharge (hh:mm): \_\_\_\_\_  
 23 \_\_\_\_\_

24 Time of discharge (hh:mm): \_\_\_\_\_  
 25 \_\_\_\_\_

26 Date of discharge: \_\_\_\_\_  
 27 \_\_\_\_\_  
 28 \_\_\_\_\_  
 29 \_\_\_\_\_  
 30 \_\_\_\_\_

### 31 Disposition

32 Home YES  NO

33 Admitted ED observation YES  NO

34 Admitted inpatient ward YES  NO

35 Admitted ICU YES  NO

36 Any general comments?  
 37 \_\_\_\_\_  
 38 \_\_\_\_\_  
 39 \_\_\_\_\_  
 40 \_\_\_\_\_  
 41 \_\_\_\_\_

### 42 Follow-up telephone call:

43 Have you sought medical attention since enrolment YES  NO

44 Was hospital re-attendance required? YES  NO

45 Was hospital admission required? YES  NO

46 for croup symptoms (i.e. stridor or breathing difficulty)? YES  NO

47 for another reason (e.g. cough, viral symptoms): YES  NO

1 (please specify):

2 \_\_\_\_\_

3 \_\_\_\_\_

4 \_\_\_\_\_

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## CROUP STUDY: INFORMATION FOR PARENTS

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Dear Parent/Carer

Your child has a condition called **croup**, which is a problem of **swelling in the airway** (windpipe), almost always caused by a **virus**.

Over the last ten years, the treatment of croup has become much more successful due to the use of **steroid medications**. A number of clinical studies have proven that a **single dose** of steroid lessens the chance of a child needing admission to hospital. These medications also shorten the length of hospital stay, decrease the need for admission to Intensive Care, and shorten the length of stay in Intensive Care.

There are **two types** of steroid medication being used for croup: **dexamethasone** and **prednisolone**. Both of these are **taken by mouth** as a small amount of syrup or liquid. The most common side-effect for both medications is **vomiting** and unfortunately neither tastes particularly nice.

Hospitals vary in their use of these medications; some use dexamethasone, while some use prednisolone. The type of steroid given to children with croup depends almost entirely on local practice (i.e. which hospital they live near). Both of these medications have been used for decades in many conditions other than croup, and have **proven safety records**. Many doctors believe that prednisolone and dexamethasone are equally as effective as each other, but it is not known for certain whether one might be slightly more effective. It is also not clear whether the lower dose of dexamethasone commonly used nowadays is as effective as the traditionally used higher dose, and this study hopes to settle this question as well.

**The aim of this study is to determine with scientific accuracy whether prednisolone and dexamethasone (in two different doses) are all equally effective for the treatment of croup.**

**If you agree** for your child to participate in this study, they will **receive either dexamethasone or prednisolone** (both are effective), decided by a random process. **Information will then be collected** about the outcome, for example whether or not your child gets admitted to hospital, and how long they stay in hospital. One of the doctors in charge of the study will **telephone** you after about one week to find out whether your child needed to return to the hospital for symptoms of

1 croup. It is expected that the number of children needing to re-attend hospital after a single dose of  
2 steroid would be very small.  
3  
4

5 Information collected during this study will be statistically analysed to determine whether the two  
6 treatments are equally effective. Results of this study may be published in a medical journal, to  
7 guide doctors treating children with croup in the future. **Patient's identities will not be revealed.**  
8  
9 All personal information relating to the participants will be destroyed after the follow-up  
10 telephone call.  
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15 **If you do not want your child to be included in this study,** they will receive treatment for croup  
16 in the usual way – the doctors will offer the type of steroid routinely used at this hospital. **Refusal**  
17 **to participate will not affect the care of your child in any way,** and consent to participate may be  
18 withdrawn at any time.  
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23 The doctor who asked you to take part in the study will be able to clarify any questions you might have.  
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## CROUP STUDY: INFORMATION FOR PARENTS: FREQUENTLY ASKED QUESTIONS

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### WHAT IS CROUP EXACTLY?

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Croup is a condition, which occurs only in children. It is caused by swelling in the lining of the airway ('windpipe'), at its narrowest part, below the vocal cords (i.e. below the larynx or 'voice-box'). This is usually due to a respiratory virus and leads to a hoarse voice, barking cough and difficulty breathing. Previous studies have shown that a single dose of steroid medication will reduce the swelling of the airway and decrease the severity and duration of the symptoms of croup.

### WHICH CHILDREN WITH CROUP NEED TO HAVE STEROID TREATMENT?

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In the past, only children with severe croup were treated with steroids, because of concern about possible side effects. Even though the chances of any side-effects are very small with a single dose of steroid, more recent clinical studies have shown that much lower doses of steroids are probably just as effective as the previously used higher doses. Doctors generally now feel much more comfortable with treating mild cases of croup with steroids, because the benefit of treatment far outweighs the possible risks.

### HOW EFFECTIVE IS STEROID TREATMENT FOR CROUP?

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Steroid medications have revolutionised the treatment of croup over the last ten years or so. Many children who would previously have needed admission to hospital can now be treated with a single dose of steroid and allowed home (sometimes after a period of observation).

It is important to note that the steroids do not treat the underlying viral infection, which caused the croup. By decreasing the swelling in the airway, steroids help to prevent increasing breathing difficulty and decrease the discomfort of breathing for the child. Unfortunately, there is no known medication to successfully treat viruses causing croup, as they are basically the same viruses as those causing the common cold in adults. Therefore, your child will continue to have a cough and other viral symptoms (runny nose, mild temperature) for the next week or longer, despite having treatment for croup.

## WHAT ABOUT SIDE-EFFECTS?

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It is widely believed by doctors that a short course of steroids of up to 5 days has little or no side effects, and a single 'one-off' dose, as used in treatment of croup, is therefore thought to be very safe.

Previous studies of croup have reported no side effects for either prednisolone or dexamethasone.

## WHAT ABOUT STEAM OR MIST THERAPY?

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Some parents report benefit from mist, for example holding a child in the bathroom whilst turning on a hot shower, but controlled studies have shown conflicting results and it probably does not work. The apparent benefit of mist therapy may be due to helping the child to calm down and 'Cuddle Therapy' is probably just as effective.

## WHY TAKE PART IN THE CROUP STUDY?

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- A chance to help improve medical knowledge on how best to treat croup.
- Standardised treatment guidelines – all participants will be assessed and treated in a similar way.
- A doctor will review your child's condition at regular intervals, in order to collect information on their clinical progress; this might improve their level of care.

## WHAT ARE THE DISADVANTAGES OF TAKING PART IN THE CROUP STUDY?

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- Receiving a telephone call from one of the doctors after one week.

If you have any concerns or questions regarding this study please contact the Medical Director at PMH via the Hospital switchboard on 08 9340 8222.