

“Acupuncture and Paediatric Post-Tonsillectomy Analgesia”

Information Sheet and Consent Form for Parents

Your child will be having a surgical operation to remove his/her tonsils and adenoids under general anaesthesia. On the day of surgery, your child will be admitted to the hospital by the nurse on the surgical ward. You may be contacted by your anaesthetist by telephone before the day of surgery to discuss your child's procedure. Otherwise, your anaesthetist will see you and your child before the operation to discuss the plan for general anaesthesia and pain management following surgery.

When your child is brought to the operating room, you will be able to accompany your child until he/she goes to sleep. The anaesthetist will use a mask with anaesthetic gas to put your child to sleep, and once your child is asleep you will be escorted from the operating room. An intravenous cannula will be inserted into your child's hand or arm, and this will generally remain in place until the following day. The surgery will then proceed, and generally will take about 30-60 minutes. When the surgery is finished, your child will be transferred to the recovery room and allowed to wake slowly from the anaesthetic. When he/she is awake and well, you should be able to come to see him/her in recovery, and you may stay with your child until they are transferred back to the surgical ward if it is agreeable with the recovery staff.

This operation is well known to be associated with significant pain and possible vomiting after the surgery. Our standard pain management after tonsillectomy surgery is regular oral Panadol, with Oxynorm liquid for breakthrough pain between doses of Panadol. Oxynorm is a narcotic-based drug that has very effective pain relieving properties, but can impair breathing if large doses are given. Our aim is not to take away all pain, but to reduce pain enough to enable your child to eat and drink while minimising the risk of respiratory depression. Most children tolerate this pain relief regimen very well, experience manageable levels of discomfort, and should be able to go home after breakfast the next day.

Recent scientific evidence suggests that the use of acupuncture may help to improve pain control and dietary intake in children after tonsillectomy. We would like to enrol your child in a trial to help establish whether acupuncture does indeed significantly improve such outcomes in children after tonsil surgery. If you agree to enrol in this study, your child will be randomly assigned to one of two groups – a control group, or a treatment group. If he/she is in the control group, he/she will receive the same standard regimen that we have been using at this hospital as outlined above. If he/she is in the treatment group, he/she will receive the standard regimen as above but with the addition of acupuncture treatment. The acupuncture will only be performed after your child is under general anaesthesia, and he/she will not be aware whether he/she has had acupuncture or not. He/she will not feel any pain from the needle insertion. All needles will be removed before he/she wakes up. The nurses in recovery and on the surgical ward will use a pain scale to assess your

child's pain level in both control and treatment groups; this will be used to compare the two groups to see if there is any difference. Our pain management after surgery is identical in both groups, and your child will otherwise be given the same treatment (as outlined above), regardless of which trial group he/she is assigned to.

Benefits:

By participating in this study, you will help us to determine whether acupuncture will benefit other children having the same procedure in future.

If your child is in the control group, he/she can be expected to have the same outcome following surgery as has always been the case. If your child is in the treatment (ie acupuncture) group, then he/she may or may not experience additional benefits as a result of the acupuncture.

Risks:

If your child is in the control group, then there is no additional risk. If your child is in the treatment group, there may be risks related to the acupuncture procedure. These risks are very small, and as described in the scientific literature, include minor bleeding (<1:100,000), nerve injury (<1:1,000,000), and infection of the acupuncture site (<1:500,000). Minor bleeding from acupuncture can generally be stopped with gentle pressure. The risk of infection is minimised by using sterile needles and by removing needles as soon as the surgery is finished.

Follow-up:

After your child has been discharged from the hospital, another anaesthetist will make a phone call to you on the following day, and also another one about 5-6 days later, to follow up on your child's progress. She will enquire about your child's pain score, using the chart below, and how much drugs the child required to be comfortable during this period after surgery.

To use the FLACC pain score, observe the child briefly and then select a score between 0 and 2 according to the criteria for each of the attributes of Face, Legs, Activity, Cry and Consolability. By adding them together, the resulting pain score should be between 0 and 10.

FLACC Pain Score

	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaints	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or "talking to". Distractable	Difficult to console or comfort

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Consent form

I, _____, (Name of Parent)

of _____, (Address)

hereby consent to my child, _____, (Name of Child)

participating in the study “ Acupuncture and Paediatric Post-operative Tonsillectomy Analgesia”.

I have read the information provided about this study, and understand the potential risks and benefits. I have had the opportunity to ask questions regarding the details and the conduct of the study.

Signed _____

Date / /