**Clinical Research - “Acupuncture and Adult Post-Tonsillectomy Analgesia”**

**Information Sheet and Consent Form for Patients**

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

When you is brought to the operating room, an intravenous cannula will be inserted into your hand or arm, and this will generally remain in place until the following day. The acupuncturist will clean your earlobes with antiseptic wipes and then insert acupuncture pads onto your earlobes. They may have very small needles on them. These should cause minimal discomfort to you and should be left in place for 5 days. If you feel pain or discomfort at any time, you can remove them. Otherwise, you should remove them after 5 days.

Once the acupuncture needles are placed on your earlobes, general anaesthesia will be induced with a mixture of intravenous drugs and you will be kept anaesthetised for the duration of procedure. The surgery will then proceed, and usually will take about 30-60 minutes. When the surgery is finished, you will be transferred to the recovery room and allowed to wake slowly from the anaesthetic. When you are awake, and comfortable with your pain relief, you will be transferred back to the surgical ward.

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 Endone tablets for breakthrough pain between doses of Panadol. Endone 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 you to eat and drink while minimising the risk of respiratory depression. Most patients 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 patients after tonsillectomy. We would like to enrol you in a trial to help establish whether acupuncture does indeed significantly improve such outcomes after tonsil surgery. If you agree to enrol in this study, you will be randomly assigned to one of two groups – a control group, or a treatment group. If you are in the control group, you will receive the same standard regimen that we have been using at this hospital as outlined above. If you are in the treatment group, you will receive the standard regimen as above but with the addition of acupuncture treatment. This will be in the form of acupuncture pads on your ears and acupuncture needles on your body. On arrival to the operating room, the anaesthetist will put an intravenous needle into your hand in preparation for the procedure. He will then put very small acupuncture needle pads onto your ear. These contains very tiny needles that should not cause you any pain. These will stay in place for 5 days and you can remove them at home by yourself unless they have already fallen out by themselves. When you are under general anaesthesia, the anaesthetist will also put body acupuncture needles on your face, hands and feet. This body acupuncture will only be performed after you are under general anaesthesia, and you will not be aware whether you have had acupuncture or not. You will not feel any pain from the needle insertion. All these body needles will be removed before you wake up. The nurses in recovery and on the surgical ward will use a pain scale to assess your 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 you will otherwise be given the same treatment (as outlined above), regardless of which trial group you are assigned to.

**Benefits:**

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

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

**Risks:**

If you are in the control group, then there is no additional risk. If you are 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 acupuncture needles, by removing body needles as soon as the surgery is finished and by removing ear acupuncture pads after a maximum of only 5 days.

**Consent form**

I, , (name)

of , (address)

hereby consent to my participation in the study “ Acupuncture and 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 / /