**Participant Information Sheet/Consent Form – Parents/Guardians**

**Interventional Study**

|  |  |
| --- | --- |
| **Title** | Does Peritoneal Lavage Influence the Rate of Complications in Paediatric Laparoscopic Appendicectomy? A Prospective Multisite Randomised Clinical Trial. |
| **Short Title** | SWAP- Sucton vs Washout for Appendicectomy in the Paediatric population |
| **Protocol Number** | 4 |
| **Coordinating Principal Investigator/ Principal Investigator** | Mr. Ramesh Nataraja  Ms. Samantha Leng  Mr. Maurizio Pacilli |
| **Location** | Monash Children’s Hospital (Monash Health)  Casey Hospital (Monash Health) |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because your child is being taken to theatre with a diagnosis of acute appendicitis.

During appendicectomy there may be some pus or debris your child’s tummy. This is always removed at the operation. After removal some surgeons like to wash the abdominal cavity with sterile saline, whereas others prefer to just remove the debris without washing. Both methods are accepted and are practiced worldwide. It is unclear if either method has more or less side effects for the patient.

The aim of this research project is to assess whether washing the inside of the abdomen during surgery for appendicitis is a worthwhile manoeuvre.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

* Understand what you have read
* Consent for you to take part in the research project
* Consent for you to have the treatments that are described
* Consent to the use of your personal and health information as described

This Participant Information and Consent Form will tell you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

**2 What is the purpose of this research?**

Appendicitis is the most common abdominal operation in children. During the procedure some surgeons wash the inside of the abdomen with saline and some do not. The aim of our study is to see if washing the abdomen makes any difference to the outcome. The rationale for washing the abdomen is to reduce the risk of infection after the operation. The reason for performing the study is that there is no objective evidence to say that washing the abdomen is better than applying suction alone without washing.

Our study will enroll 616 patients into a washout group and 616 patients into a no washout group. We will follow the patient after the surgery to see if there is any difference between the two groups. The study is being performed at many hospitals across Australia, includingMonash Children’s Hospital and Casey Hospital (Monash Health)**.**

**3 What does participation in this research involve?**

If your child is enrolled in this study he/she will have his/her appendix removed in the standard fashion. During the operation he/she will be allocated randomly to either the washout group or no washout group. Your child’s care after the surgery will not be affected. He/she will receive antibiotics for 5 days and will be assessed twice daily. We will also review your child in outpatients 4-6 weeks after the operation.

**4 What does my child have to do?**

Your child does not have to do anything differently.

The details of the study, potential risks, requirements of you should you consent for your child to participate and the aims of this study should be clarified to you prior to the operation.

By providing consent, you are permitting your child’s participation in all aspects of the study. If your child fails to complete an aspect of the follow-up after the operation, their results will not be used for that part of the study but results from all other aspects of follow-up which have been completed will be used. If you choose to withhold some of the information required for the purposes of this study, your child’s results may not be used if the information withheld is important for the analysis.

At any point in the study, should you have any questions, concerns or complaints, these can be discussed with the Principal Investigators.

**5 Does my child have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish for your child to take part, they do not have to. If you decide to allow your child to take part and later change your mind, you are free to withdraw them from the project at any stage.

If you do decide to allow your child to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to allow your child to take part or not to take part, or to take part and then withdraw, will not affect their routine treatment, their relationship with those treating them or their relationship with their treating hospital. Choosing not to provide consent for your child’s participation or requesting for your child’s participation to be withdrawn will have no impact on their operation. Regardless of your decision, their surgery will proceed as scheduled, be performed as per normal and they will receive the usual postoperative care. The surgical method (washout or no washout) used will be that chosen by the operating surgeon.

**6 What are the alternatives to participation?**

Your child do not have to take part in this research project to receive treatment at this hospital. If you choose not to allow them to participate in the study, the surgery will continue as per normal and the surgical method (washout or no washout) used will be that of the surgeon’s personal preference. Your child will receive the usual postoperative care.

**7 What are the possible benefits of taking part?**

We cannot guarantee or promise that your child will receive any benefits from this research; however, possible benefits may include a quicker recovery after the operation depending on which group you enter.

Knowledge gained from this research may modify how surgeons perform appendicectomy and therefore may benefit patients in the future.

**8 What are the possible risks and disadvantages of taking part?**

The possible risks of being involved in this surgery are minimal. Currently, when a child undergoes an appendicectomy they will either have the inside of their abdomen washed out or not depending on the performing surgeon’s preference. Our study will simply be formalising which treatment each patient receives and monitoring the outcome to see if there is any difference. We are not performing any new or novel procedure, just assessing two currently acceptable modes of practice. The possible risk of being involved is the development of infection after the surgery.

There may be additional risks that the researchers do not expect or do not know about. Tell a member of the research team immediately about any new or unusual symptoms that you get.

**9 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the Principal Investigator/s will tell you about it and discuss with you whether you want to allow your child to continue in the research project. If you decide to withdraw your child, your study doctor will make arrangements for their regular health care to continue. If you decide to continue your child’s participation in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your child’s best interests to withdraw them from the research project. If this happens, the reasons will be explained to you and arrangements made for their regular postoperative care to continue.

**10 Can my child have other treatments during this research project?**

Your child will be followed after his/her operation as an inpatient as would normally occur during the recovery period following appendicectomy. Being part of this trial will not affect any other condition your child may have.

**11 What if I withdraw my child from this research project?**

If you decide to withdraw your child from the project, please notify a member of the research team before you withdraw them. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing. Your child will receive usual medical care if you choose to withdraw them from the study. There will be no implications to their ongoing medical management or their relationship with their treating hospital, treating team and treating doctor/s.

If you do withdraw your consent for your child’s participation during the research project, the study doctor and relevant study staff will not collect additional personal information from you or your child, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

**12 Could this research project be stopped unexpectedly?**

It is possible that this study could be stopped unexpectedly due to unexpected results. In this case the participants will be informed immediately.

**13 What happens when the research project ends?**

Your child will be followed up postoperatively as described previously as part of the post-operative follow-up. Following this, your child may have further follow-up as clinically required but they will not be further followed up for the purposes of this research project.

Once the results have been collated and analysed, the information related to your child’s participation in the study and results will be retained in a secure format for at least 23 years following completion of the study,after which they will be appropriately disposed of in a confidential fashion.

Once we have analysed the results, we will publish the overall results of the study on the Department of Paediatric Surgery at Monash Children’s Hospital website. Your child’s results will be de-identified and in no way will their individual results be identifiable.

**Part 2 How is the research project being conducted?**

**14 What will happen to information about my child?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about your child for the research project. Any information obtained in connection with this research project that can identify your child will remain confidential. Your child’s information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Your child’s results from this study gathered pre-operatively and at each of the follow-up appointments after the surgery will be securely stored in an electronic format and will not be individually identifiable. All paperwork will be stored in a locked cabinet in the offices of the the involved Departments. Information collected will only be accessible by the Principal Investigators and not be disclosed to any third party. Following the conclusion of the study and data analysis, information and data from the study will be retained in a secure format for at least 23 years following completion of the study. After this, it will be appropriately disposed of in a confidential fashion.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, except with your permission.

Once we have analysed the results, we will publish the overall results of the study on the Department of Paediatric Surgery at Monash Children’s Hospital website. Your child’s results will be de-identified and in no way will their individual results be identifiable. Your child’s identity will not be revealed in any publication arising from the research and all results presented for the study will be for those of the overall treatment group. Your child’s individual results will not be provided and in no way will any of the results be identifiable. The results of this study may be published in a medical journal if accepted for publication. Information about your child’s participation in this research project may be recorded in their health records.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your child’s information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact one of the study team members named at the start of this document if you would like to access your child’s information.

Any information obtained for the purpose of this research project that can identify your child will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**15 Injury**

It is extremely unlikely that your child will be injured as a result of participating in this research project as we are not using any new intervention or treatment, we are simply analysing what our normal treatment in a formal way. If your child suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment for your child. If your child is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**16 Who is organising and funding the research?**

This research project is being conducted by Mr. Ramesh Nataraja, Ms. Samantha Leng, and Mr Maurizio Pacilli. There is no external funding nor are there any sponsors for this study. The Principal Investigators do not have any conflicts of interest to declare.

**17 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Monash Health (Monash Health Human Research Ethics Committee).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**18 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the clinical contact person listed below or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | Monash Health Human Research Ethics Committee |
| HREC Executive Officer | Ms. Deborah Dell (Monash Health HREC Manager) |
| Telephone | **(**03) 9594 4611 |
| Email | research@monashhealth.org |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site – Research Governance Officer)**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

**Consent Form – Parent/Guardians**

|  |  |
| --- | --- |
| **Title** | Does Peritoneal Lavage Influence the Rate of Complications in Paediatric Laparoscopic Appendicectomy? A Prospective Randomised Clinical Trial. |
| **Short Title** | Insert creative name here |
| **Protocol Number** | 2 |
| **Coordinating Principal Investigator/ Principal Investigator** | Mr. Ramesh Nataraja  Ms. Samantha Leng  Mr. Maurizio Pacilli |
| **Associate Investigator(s)** | TBC |
| **Location** | Monash Children’s Hospital (Monash Health)  Casey Hospital (Monash Health)  The Royal Children’s Hospital |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand. I understand the purposes, procedures and risks of the research described in the project.

I give permission for my child’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the relevant hospital where this study is being conducted – **[INSERT SITE]** – concerning my child’s disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received. I freely agree to allow my child to participate in this research project as described and understand that I am free to withdraw my child at any time during the study without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

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| Name of Child (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Parent/Guardian (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Signature of Parent/Guardian \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

**6-Month Follow-Up Contact Details**

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| --- | --- |
| Contact details for study follow-up:  Telephone \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

**Form for Withdrawal of Participation – Parents/Guardians**

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| --- | --- |
| **Title** | Does Peritoneal Lavage Influence the Rate of Complications in Paediatric Laparoscopic Appendicectomy? A Prospective Randomised Clinical Trial. |
| **Short Title** | Insert creative name here |
| **Protocol Number** | 2 |
| **Coordinating Principal Investigator/ Principal Investigator** | Mr. Ramesh Nataraja  Ms. Samantha Leng  Mr. Maurizio Pacilli |
| **Associate Investigator(s)** | TBC |

**Declaration by Participant**

I wish to withdraw my child from participation in the above research project and understand that such withdrawal will not affect my child’s routine treatment, their relationship with those treating them or their relationship with **[INSERT HOSPITAL HERE]**.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant’s parent/guardian has understood that explanation.

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| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.