CONTRACT

University Hospital Southampton NHS
NHS Foundation Trust

CONservative TReatment of Appendicitis in Children – a randomised controlled Trial (Feasibility)

PARENTS INFORMATION SHEET

We are asking you and your child to take part in a research project. Before you decide it is important that you understand why the research is being done and what it will mean for you and your child. You should discuss this with your doctor. Please ask us if there is anything else that is not clear or you would like to know.

Why do we do research in healthcare?
Research is really important so that we can improve how we treat patients. If no research took place then it would be difficult to improve outcomes for patients. All research in the NHS is voluntary.

Why are we doing this research?
Your child has been diagnosed with acute appendicitis which means inflammation of the appendix. The standard treatment of acute appendicitis is an operation to remove the inflamed appendix. Parents often ask if children with appendicitis can be treated without an operation. Recently some studies have shown most children with appendicitis can be treated with antibiotics instead of an operation. But no studies in children have compared the advantages and disadvantages of having antibiotic treatment instead of surgery. The purpose of our study is to see if children with acute appendicitis can be treated equally effectively with antibiotics as with the standard operation. The study will also show if there are extra benefits of having antibiotics instead of surgery.

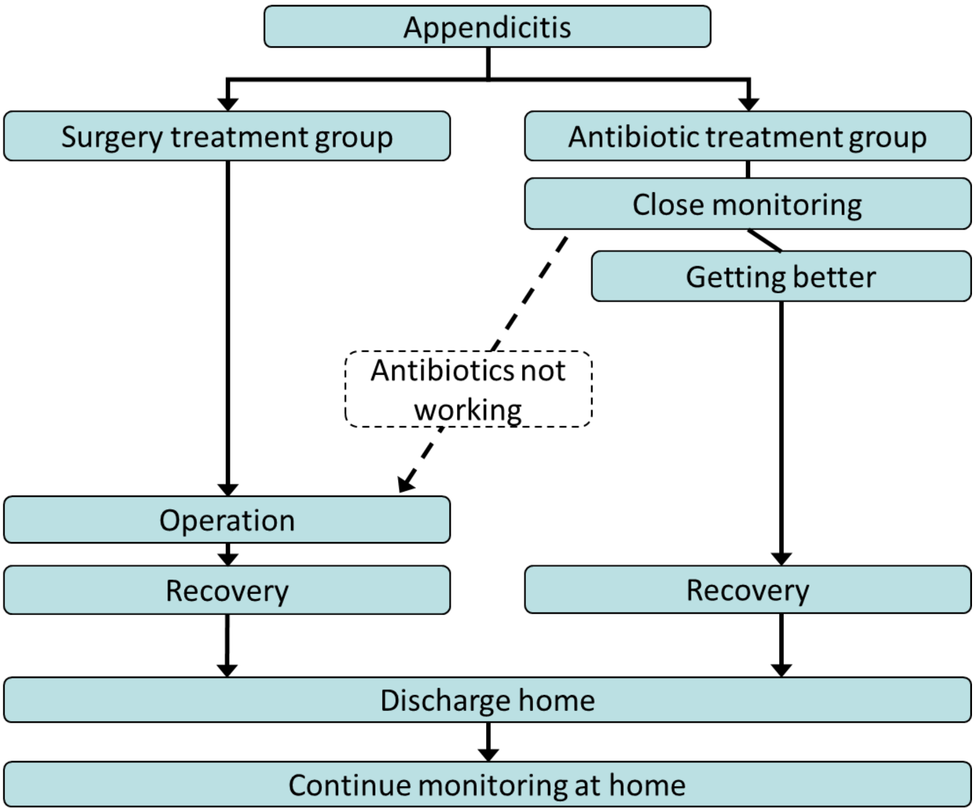
What will happen to my child if we do take part?
If you agree to take part in the study we will use a computer to decide at random whether your child will have their appendicitis treated with just antibiotics or with an operation. The chance of treating with either antibiotics or surgery is equal. Even if you don’t consent to your child taking part in this study, we will still treat your child for their appendicitis.

Operation Group: If your child is treated with surgery, he/she will have an operation to remove the inflamed appendix. This will require general anaesthesia and one or more small scars on the tummy. Your child will be monitored by nurses and doctors before and during the operation, and afterwards on the ward. Once your child is stable, able to take fluid, food and painkillers by mouth, and move around, he/she will be allowed home.

Antibiotic Treatment Group: If your child is treated with antibiotics, he/she will receive antibiotics through a drip and not take any food or fluid for a minimum of 12 hours. Your child will be monitored on the ward by nurses and doctors. Once we are happy that your child is improving we will change to antibiotics by mouth. When it is clear your child is getting better, able to take fluid, food and painkillers by mouth, and move around your child will be allowed home. Your child will need to continue taking antibiotics by mouth for about a week.

Children in both groups will be monitored closely during their time in hospital to make sure they are getting better. When you go home you will be given information about who to contact if you are concerned about your child’s recovery. You will be seen in the outpatient clinic at 6 weeks (as is current routine care). For the purposes of this research project we will ask you to visit us again in the clinic or contact you by telephone after 3 months and 6 months. At these visits and during the stay in hospital we will ask you to fill in a short questionnaire about your child's health status. We will give you an extra questionnaire at discharge to fill in and return 2 weeks after you have gone home. With your permission we will also keep your contact details for a maximum of 5 years as we may wish to contact you to check on your child's progress in the future.

The figure below gives an overview of how the study works



What are the risks and benefits?
It is important that you and your child understand the risks and benefits of each of these options.

<u>An operation:</u> Having an operation will require general anaesthesia and involves a small number of risks related to surgery including bleeding, wound infection, a collection of pus in the abdomen, and in rare cases bowel obstruction requiring further surgery. There is also a 10% chance that the operation may show a healthy appendix, which means that the surgery was not necessary. In this case we will remove the appendix anyway. The benefit of an operation is that we know that surgery is an effective treatment for appendicitis.

<u>Antibiotics:</u> If your child is treated with antibiotics, there is a small risk that antibiotic treatment may not work. However, data we have collected on children such as yours who have been treated with antibiotics suggest that it works in the majority of cases (97%). We will monitor your child closely whilst he/she is in hospital and if there is no improvement with antibiotic treatment, he/she will have an operation to remove the appendix. The other risk of antibiotic treatment is that your child will still have his/her appendix and may get appendicitis again. If this were to happen then we would remove the appendix. Based on the research that has been done so far, we believe the risk of this is low (about 14% or 1 in 7 children in the first year). The potential benefit of antibiotic treatment is that your child may avoid an operation and general anaesthesia altogether.

What are the potential benefits of taking part?

This study will not bring any immediate benefit to your child. We hope that we will get information about how best to treat children such as yours in the future. After we have finished the study we can let you know the results if you would like. We do hope that the information gained from this study will be beneficial to children with appendicitis and their families in the future. By participating, you will be helping us to learn whether treatment with antibiotics is as good as surgery so that we may be able to offer this routinely as a treatment for other children in the future.

CONTRACT Communication study

In addition to the main study comparing antibiotics and surgery, we would also like to talk to people about their feelings about this study so that we can improve the ways that we communicate with families about studies like this in the future. It is important for us to talk to people who agree to take part in the main study as well as those who decide not to. With your permission we would like to record the conversation you have with the doctor and nurse about this study. We may also ask if a researcher from the Communication Study can contact you in a few weeks time to talk to you about your experience of being involved in the study. Again we will ask you for your permission to record this conversation.

Who is funding the research?

This project is funded by the National Institute for Health Research, which is the research arm of the NHS.

Will we be paid for being part of the study?

You and your child will not be paid to participate in the study. However we will reimburse your expenses for each of the additional follow-up appointments you attend at 3 and 6 months after going home (maximum £10 per visit).

Where is the study taking place and who is running it?

The study is being run by a group of surgeons at 3 specialist centres in the UK. Initially we are doing a small study in these 3 hospitals to figure out if this research is feasible. If it is feasible, we want to extend this to a much larger study. We also have a group of researchers interested in what influences children and families to take part in research studies. A group of parents and children are also helping to make sure the study is as child and family friendly as possible. For instance they have helped us write this information sheet.

The overall research study is being sponsored by University Hospital Southampton NHS Foundation Trust and is being co-ordinated by the Southampton Clinical Trials Unit.

Do I have to take part?

No, taking part is up to you and your child. If you decide not to take part you do not have to give a reason and your child's treatment will not be affected in any way. Your child will receive the standard treatment which your child's doctors will discuss with you. If you choose to let your child take part in this study you can take your child out of the study at any time.

How long do I have to decide?

Because we would like to start treating your child soon we will need to know if you are willing to take part within the next four hours. To help you decide please talk about the project to your research nurse and doctor. Please ask them any questions you may have.

If you agree to take part we will ask you to sign a consent form which indicates your agreement to take part in the research project and to let the researchers look at your child's health records. We will put a copy of this research consent form in your child's patient health records. We will give you a copy for your files.

Who will know that I am taking part in the study?
All the information we keep about your child and all conversations we record will be kept confidential. This means that we will only tell those people who need to know. This will include members of the research team for the purposes of contacting you during the study. With your permission we will let your child's GP know that he/she is taking part in this study.

Employees of the sponsor of the study, or the regulator of the study may need to see your child's health record to check on the study – this is a routine process of research in the NHS.

Availability of Research Results
The results of the study are likely to be published in medical journals. You and your child's name will not be identified in any report or publication. If you would like, we will also send a summary of the results of the study to you and your family doctor or paediatrician.

What are the arrangements for compensation?
All research in the NHS is looked at by a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the South Central – Hampshire A Research Ethics Committee.

If taking part in this research study harms your child, there are no special compensation arrangements. If your child is harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay legal costs. Regardless of this, if you wish to complain, or have concerns about any aspect of the way you or your child have been approached or treated during the course of this study, the normal National Health Service complaints mechanism will be available to you.

If you have private medical insurance, you may wish to check with your company before agreeing to take part in the study to ensure that participation in the study will not affect your insurance cover.

Details on how to contact the researchers:
If during the course of the study, you have any questions regarding your child's participation or would like study specific information, please contact.

Local Principal Investigator
Name of local PI
Local PI contact details (email and phone)

Chief Investigator for the overall study
Mr Nigel Hall
Consultant Paediatric Surgeon
Southampton Children's Hospital
n.j.hall@soton.ac.uk

In case of complaint please contact the Patient Support Services for advice:

Address, phone and email of local PALS service

Thank you for taking the time to read this information sheet

A copy of this sheet should be given to the parents and a copy placed in the child's medical record.