



CONTRACT 

University Hospital Southampton 
NHS Foundation Trust

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

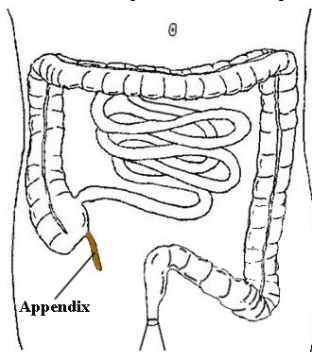
INFORMATION SHEET FOR TEENAGERS (12-15 yrs)

We are asking you to take part in a research project. Before you decide we want to explain to you a bit about the project and what it will mean for you. You should talk to you parents about it. If there is anything that you want to know or do not understand please ask us.

Why are we doing this research?

You have come into hospital with stomach pain and your doctors think you have an illness called appendicitis. Your appendix is a little tube attached to your large intestine that has no function at all! It doesn't usually cause any problems, unless it becomes infected, when it becomes red and sore. This is called appendicitis.

Inside your tummy



We are doing a project to learn about how *best* to treat children with appendicitis. Up to this point, all children needed an operation to remove the appendix. Although the operation works very well, we *now* know that it's also possible to treat appendicitis just with medicines called antibiotics. It could be better and easier for children and their families if an operation was not necessary.

So, in this project we want to find out whether the usual operation, or giving kids antibiotics, works better to get rid of appendicitis.

To do this, in the project some children will have an operation and some will just have the antibiotics. By comparing these treatments we hope to be able to tell if children really need surgery for appendicitis or if they can be treated just as well with antibiotics

What will happen to me if I do take part?

If you and your parents agree to be in our project, we will ask a special computer program to decide which treatment you will have, a process that is called 'randomisation'. One treatment will be the operation, one treatment will be antibiotics. It's important to have the computer program do this for us, so that everyone has the same chance of either having the antibiotics, or having the operation. You will only have one treatment, and **even if you don't want to take part in this study, we will still need to treat you for your appendicitis.**

If you have **an operation** this takes about an hour and is done whilst you are asleep. You will have one or more small cuts on your stomach and need to be in hospital for a day or 2 afterwards. You'll probably have some pain in your stomach and not be able to run around or be as active as you usually are for a while after the operation, even after you go home.

If you have **antibiotics** then these will be given through a drip. This is a small and usually painless tube in your hand or arm. We will ask you not to eat or drink for about 12 hours. You will need to spend at least 24 hours in hospital. Once you are getting better we will give you antibiotic medicine by mouth, and send you home. You will need to carry on taking the medicine for just over a week.

No matter which treatment you receive (operation or antibiotics), we will keep a very close eye on how you are doing to make sure that you are getting better. You will need to stay in hospital for a

bit and have some medicines through a drip. We will give you pain killers to help decrease your pain.

Once you have got better and gone home we will ask you to come back several times in the first 6 months so we can check up on you.

As an extra part of the project we will also ask you and your parents if we can record the conversation when we talk to you about the project. This is so we can find out what people think of the study and improve it in the future. We may also ask if it is OK to visit you at home in a few weeks time to ask you what you thought of the project.

Do I have to take part?

No, taking part is up to you and your parents. If you do decide to take part then you will be asked to sign a form to say you agree to take part. You can keep this sheet to read. You can ask questions about this study at any time.

If you decide at any time not to go ahead with all the things that are involved in the study, you can ask us to stop. (So, for example, if you decide after you leave the hospital that you don't want us to check in with you anymore, that's perfectly OK.)

If you decide not to take part in the study whatsoever, you do not have to give a reason and no one will be upset or disappointed. Don't worry, whatever you decide about taking part in this project, we'll still treat you for your appendicitis and take very good care of you.

What are the risks?

All treatments that doctors do carry a small number of risks. The risks of having an operation are that there is a small chance of developing a problem after the operation, which we would have to treat (such as an infection). We may also find that you don't actually have appendicitis in which case you would have had an operation that you didn't need.

The main risk of being treated with antibiotics is that they don't make you better as quickly as we hope. This is very unlikely and because we will be keeping a close eye on you we will know about this. If this is the case we will have to go ahead with the usual operation to remove your appendix. The other risk is that you may get appendicitis again. The risk of this is low (about 1 in 7 children). If you are unlucky and this happens then we will definitely do the operation to remove your appendix. This is the reason we would like you to come back to visit us after you have been in hospital – so we can make sure you are doing OK.

Will taking part help me?

Taking part will not actually help you physically because we'll treat your appendicitis anyway, but we hope that it will help children like you in the future. Some children like taking part in studies because they find it interesting to learn more about research, and to help other children. After we have finished the project we can let you know the results if you are interested.

Who will know that I am taking part in the study?

We will only tell those people who need to know including your family doctor.

How to contact the researchers

If during the course of the project you have any questions, please feel free to contact your doctor or nurse. These details can be found on your Parent's Information sheet

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