

NESSTAC



North of England and Scotland Study of Tonsillectomy and Adeno-tonsillectomy in Children

The Tonsil Study Information for Children



How would you like to take part in a research study?

Before you decide, we want to tell you about the study and what taking part in it would mean for you. Please read this leaflet and talk to your parents or other people about it if you want to. Because the leaflet talks about medical treatments, you may not know some of the words. Just ask the nurse or doctor about anything that is not clear. They will be very happy to answer any questions you have.

Thank you for reading this.

What is the tonsil study?



Having your tonsils out (also called a "tonsillectomy") is a very common operation. But we are not sure whether it is always the best thing to do with children like you. Some doctors think it might be better to wait and see whether children like you get better as they get older rather than having an operation now. At the moment no-one knows the answer. This is what the tonsil study is trying to find out.

Why have I been chosen?



We are asking all children, aged between 4 and 15, who visit this hospital because they get lots of sore throats, to take part in the tonsil study. We need 400 children altogether.

Do I have to take part?



No – you don't have to take part if you don't want to. Nobody will be cross with you if you say that you don't want to take part. If you say yes now but change your mind later, that's OK too. But if you do take part you will be helping to answer an important question which is bothering doctors and nurses around the country.

What will happen if I take part?



If you decide to take part you will be put at random into one of two groups. "At random" is like tossing a coin, or pulling a name out of a hat. Except that in this case a computer does it. Neither you nor anyone else will be able to choose which group you get put into.

- The first group is the "wait and see group". This group will carry on seeing their family doctor when they need to for any sore throats or tonsillitis they get. Plus, they will see the hospital doctor in about 9 months time to check how they are doing.
- The second group is the "tonsils out group". This group will be put on the list to have their tonsils out.

You will have the same chance of being in one group as the other.

Whichever group you are in, we will ask you to answer some questions about your health. We will do this by giving you some questionnaires and a diary to fill in. The diary isn't like a diary where you write in sentences about what you did on holiday. In this one we just ask you to circle some numbers. The research nurse can show you the questionnaires and diaries now if you would like to see them. If you decide to take part in the study, the research nurse will show you how to fill in the questionnaires and diaries.

Are there any risks to taking part?



All medical treatments carry some risks. For example, medicine to treat sore throats sometimes gives children an upset tummy. The treatments in the tonsil study are not new and lots of children have had them before. So there are no special risks to taking part. We just don't know which treatment is best. The normal risks that you can expect with the treatments in the tonsil study are:

1. Wait and see group

There is a high chance that children who don't have their tonsils out will get at least one extra sore throat or attack of tonsillitis. As you know, this can be unpleasant but it usually clears up within a few days without any serious problems. Sometimes, a sore throat leads onto another problem like an ear infection. Very rarely, a sore throat gets so bad that a child has to go into hospital.

2. Tonsils out group

If you have your tonsils out you will have to have a stay in hospital. You will be put to sleep while the doctor takes your tonsils out. After the operation you will probably feel a bit sick and have a sore throat. You will have to have some time off school. Some children get an infection or have bleeding after the operation.

Will I get anything out of taking part in the study?



Both the treatments in the tonsil study are safe and help children with sore throats. But you won't get any special treatment because you're taking part in the tonsil study. We hope that you will feel proud to be helping answer an important question about children's health. This will help us to treat children with sore throats and tonsillitis better in the future.

Will you tell anyone what I say?



We will keep all the information we collect about you private and confidential.

We will need to tell your family doctor that you are taking part in this study, and that you have said it is OK for us to look at your medical records. But we will not tell your family doctor, or anyone else, anything that you tell us, unless you ask us to.

The only time we might have to tell somebody about something you tell us, is if you tell us something that makes us very worried about you. But we would still try and check with you first before we told anyone.

What will happen to the results of the research study?



The results of the research study will go to the doctors and nurses so that they will know better how to treat children with tonsillitis. If you'd like to know the results of the research study please tell us.

I want to ask another question about the tonsil study



Just ask the nurse or the doctor at the hospital. Their names are at the bottom of this page.

Newcastle upon Tyne:
Professor J Wilson and Mr S Carrie
Liverpool: Mr R Clarke
Manchester: Mr A Zarod
Bradford: Mr C Raine
Glasgow: Mr H Kubba
Mrs Mary Dickinson
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Freeman Hospital

Royal Liverpool Children's NHS Trust
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Booth Hall Children's Hospital

Bradford Teaching Hospitals NHS Trust
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Royal Hospital for Sick Children (Yorkhill)

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North of England and Scotland Study of Tonsillectomy and Adeno-tonsillectomy in Children



Teenager Information Sheet

Randomised controlled trial

Would you like to take part in a research study? Before you decide we want to tell you why the research is being done and what it will involve. Please read this leaflet and talk to your parents or other people about it if you want to. Ask the nurse or doctor about anything that is not clear. They will be very happy to answer any questions you have. Thank you for reading this.

What is the NESSTAC study?

Having your tonsils out (also called a “tonsillectomy”) is a very common operation. But we are not sure whether it is always the best thing to do with teenagers like you. Some doctors think it might be better to wait and see whether teenagers like you get better as they get older rather than having an operation now. At the moment no one knows what’s best. This is what the NESSTAC study is trying to find out.

Why have I been chosen?

We are asking all children and teenagers, aged between 4 and 15, who visit this hospital because they get lots of sore throats, to take part in the tonsil study. It is important that we have lots of teenagers as well as younger children. We need 400 children and teenagers altogether.

Do I have to take part?

It is up to you to decide whether or not to take part. Nobody will be annoyed with you if you say that you don’t want to take part. If you say yes now but change your mind later, that’s OK too. We are not paying your doctor to include you in the NESSTAC study. But if you do take part you will be helping to answer an important question which is bothering doctors and nurses around the country.

What is a randomised controlled trial?

When we do not know the best way of helping people with an illness, we need to compare different treatments. For the comparison to be fair, we need to make sure that the sort of people in each group are exactly the same. We do this by putting people into groups “at random” – which is rather like tossing a coin, or pulling a name out of a hat. Except that in NESSTAC a computer does it.

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Randomised controlled trials are only ever carried out when doctors are not sure which way of treating people is best – if it were clear that having your tonsils out would be best for you then you would not be being asked to take part in this trial.

What will happen if I take part?

If you decide to take part in the NESSTAC study, you will be put at random into one of two groups.

- The first group is the “wait and see group”. This group will carry on seeing their family doctor when they need to for any sore throats or tonsillitis they get. Plus, they will see the hospital doctor in about 9 months time to check how they are doing.
- The second group is the “tonsils out group”. This group will be put on the list to have their tonsils out. [It is possible that they may also have their adenoids out at the same time (this is called an adeno-tonsillectomy). Having the adenoids out as well is quite normal when having your tonsils out. If this happens to you it will be because the doctor doing the operation thought it was necessary. This decision has nothing to do with the NESSTAC trial.]

You will have a 1 in 2 (or 50/50) chance of being in either group. Neither you nor anyone else will be able to choose which group you get put into. You therefore need to be happy whichever group you get put into if you are going to take part in the trial.

Whichever group you are in, we will ask you to answer some questions about your health. We will do this by giving you some questionnaires and a diary to fill in. The diary isn't like a diary where you write in sentences about what you did on holiday. In this one we just ask you to circle some numbers. The research nurse can show you the questionnaires and diaries now if you would like to see them. If you decide to take part in the study, the research nurse will show you how to fill in the questionnaires and diaries.

If you do not think you would be prepared to fill in these questionnaires and diaries then you should not agree to take part in the trial.

Are there any risks to taking part?

All medical treatments carry some risks. For example, antibiotics to treat sore throats sometimes gives people an upset stomach. The treatments in the tonsil study are not new and lots of children and teenagers have had them before. So there are no special risks to taking part. We just don't know which treatment is best. The normal risks that you can expect with the treatments in the tonsil study are:

1. Wait and see group

There is a high chance that children and teenagers in the study who don't have their tonsils out will get at least one extra sore throat or attack of tonsillitis. As you know, this can be unpleasant but it usually clears up within a few days without any serious problems. Sometimes, a sore throat leads onto another problem like an ear infection. Very rarely, a sore throat gets so bad that a person has to go into hospital.

2. Tonsils out group

If you have your tonsils out you will have to have a stay in hospital. You will be put to sleep while the doctor takes your tonsils out. After the operation you will probably feel a bit sick and have a sore throat. You will have to have some time off school. It's possible you could get an infection or have bleeding after the operation.

Will I get anything out of taking part in the study?

Both the treatments in the tonsil study are safe and help children and teenagers with sore throats. But you won't get any special treatment because you're taking part in the tonsil study. We hope that you will feel proud to be helping answer an important question about children and teenagers' health. This will help us to treat children and teenagers with sore throats and tonsillitis better in the future.

Will you tell anyone what I say?

We will keep all the information we collect about you private and confidential.

We will need to tell your family doctor that you are taking part in this study, and that you have said it is OK for us to look at your medical records. But we will not tell your family doctor, or anyone else, anything that you tell us, unless you ask us to.

The only time we might have to tell somebody about something you tell us, is if you tell us something that makes us very worried about you. But we would still try and check with you first before we told anyone else.

What will happen to the results of the research study?

The results of the research study will go to the doctors and nurses so that they will know better how to treat children and teenagers with tonsillitis. If you'd like to know the results of the research study please tell us.

I want to ask another question about the tonsil study

Just ask the nurse or the doctor at the hospital. Their names are at the bottom of this page.

For more information please contact:

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Parent Information Sheet

Randomised controlled trial

You and your child are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the NESSTAC study?

Tonsillectomy ("having your tonsils out") is a very common operation in Britain and other countries. Usually it is carried out on children who have lots of sore throats or tonsillitis. It is a safe operation but has never been properly tested to see whether it leads to a long-term improvement in children's health. On the one hand having tonsils out clearly means that the tonsils can no longer become infected. On the other hand, tonsillectomy means a general anaesthetic, a stay in hospital and the discomfort associated with having surgery. Children who have their tonsils out may still get other sore throats. And children who suffer from tonsillitis but *don't* have their tonsils out often "grow out" of tonsil infections after a year or two.

At one time it was routine for children suffering from lots of sore throats or tonsillitis to have their tonsils out. Doctors nowadays are not so sure that this is the right thing to do. In the UK an average of 2.3 children in every 1000 children will have their tonsils removed. But within the UK the rate varies a lot from place to place. And in some other countries such as Germany it is much less common to have your tonsils out.

Because of the uncertainty about what is best to do for children who get sore throats and tonsillitis, the National Health Service (NHS) has funded the University of Newcastle, together with hospitals in Newcastle, Manchester, Liverpool, Bradford and Glasgow, to carry out a randomised controlled trial of treatment for sore throat or tonsillitis. This study started in 2001 and should finish in 2008.

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Why has my child been chosen?

All children aged between 4 and 15 who are referred for sore throats and tonsillitis to the 5 hospitals taking part in the study are being considered for this trial. We need to include 400 children in the trial.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you are still free to opt out at any time and without giving a reason (though it may help the researchers if you do give a reason). Your child will get the best possible care as a patient no matter what you decide to do. Your doctor is not being paid to include you in the NESSTAC trial.

What is a randomised controlled trial?

When we do not know the best treatment, we need to compare different approaches. For the comparison to be fair, we need to make sure that there is no difference between the people in the groups that are being compared. We do this by putting people into groups randomly – which is rather like tossing a coin.

In the case of NESSTAC, a central computer is used to decide which group people are put into. Neither you nor your doctor can choose which group your child is put into. You therefore need to be happy with whichever group your child gets put into if you are going to be involved in this trial.

Randomised controlled trials are only ever carried out when doctors are not sure which way of treating people is best – if it were clear that having your tonsils out would benefit your child then you would not be being asked to take part in this trial.

What are the comparison groups in NESSTAC?

In the NESSTAC trial, children will be put, by chance, into one of **two** groups.

- The first group will be medical management. This means that they will continue to have treatment from their GP for any bouts of sore throat or tonsillitis. In addition they will be given a follow up appointment to see the hospital doctor in 9-12 months time to check how they are doing. At this time, you and your hospital doctor can think again about whether having your child's tonsils out would be a good idea. This type of approach is sometimes called "watchful waiting".
- The second group will be surgical treatment. This means that they will be put onto the waiting list to have their tonsils out now. They may also have their adenoids out at the same time (this is called an adeno-tonsillectomy) if the doctor thinks this is necessary. [Having the adenoids out as well is quite normal. If this happens to your child it will be because the surgeon and you are agreed that this is necessary. This decision has nothing to do with the NESSTAC trial.] While children are waiting to have their tonsils out they should see their family doctor or GP as usual for any bouts of sore throat or tonsillitis.

Your child will have a 1 in 2 (or 50/50) chance of being in either group. Once your child has been assigned to one of the groups you are still free to switch to the alternative course of treatment without having to withdraw from the trial.

What will happen if I agree to take part?

First, you will be asked to sign a consent form to show that you are happy to take part in the study. You will also be asked to sign to say that you are happy for a data collector to get some information about your child's sore throats from the GP's records, at the end of the study. If there is anything on the consent form, or in this

information sheet, that you do not understand or agree with please tell the nurse before you sign the form. You will be given a copy of your signed consent form and of this information sheet to keep.

Next your child will be randomised to either the surgical (tonsillectomy) or the medical (GP and hospital follow up) group.

Whichever group you are in, you will be asked to complete 4 questionnaires over the next 2 years. These questionnaires will have questions about your child's health, and the impact of any illnesses they have on both you and your child. Some of these questions will be about the costs to you of your child's illnesses. If your child is aged 8 or over then there will be separate questionnaires for them to fill in. We will also want you to complete weekly diaries of sore throat symptoms. We estimate that the diary will take 5 minutes a week to fill in and that each questionnaire should take no more than 15 minutes to complete. We will post these out to you with a reply paid envelope for you to return them to us. The research nurse can show you the questionnaires and diaries now if you would like to see what they will involve. If you decide to take part in the study, the research nurse will show you how to complete the questionnaires and diaries. If you do not think you would be prepared to fill in these questionnaires and diaries then you should not agree to take part in the trial.

What are the possible disadvantages and risks of taking part?

All the treatments being used in the NESSTAC trial are part of normal medical care – there are no special risks from taking part. The normal risks associated with each of the treatment options are outlined below.

1. Medical management group

There is a high chance that children in the medical management group will suffer at least one additional bout of tonsillitis. As you know, this can be unpleasant but it usually clears up within a few days without any serious problems. There is a small risk that a bout of tonsillitis could lead on to another problem such as an ear infection, and an even smaller risk that a bout of tonsillitis could become more serious and require hospital treatment. It is difficult to give numbers for these risks. Some studies have shown complications happen after tonsillitis in about 1% of cases. But this includes figures for adults and complications are less common in children.

2. Surgical treatment group

As with any operation, there are some risks associated with tonsillectomy but these are small. The main risks are of infection and haemorrhage (severe bleeding) after the operation. Around 2% of children may have a haemorrhage – this means that out of the 200 children who will be in the NESSTAC surgical treatment group we might expect 4 to have a haemorrhage. Some of these children may need another operation. More common side effects include feeling sick or being sick, and minor bleeding after the operation. There is also likely to be a sore throat – typically this may be like that felt during a bout of tonsillitis.

Any person or parent consenting to undergo tonsillectomy should understand that there have been, over the past 20 years in the UK a very small number of cases of fatal haemorrhage following tonsil removal. This is a potential risk in any type of surgical operation and fortunately in the present day is extremely rare indeed.

What are the possible benefits of taking part in the study?

There are no direct benefits to you and your child from taking part in the study. But you will be helping to answer an important question about children's health. The aim of the study is to treat future children with sore throats and tonsillitis better.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital or the GP surgery will have your name and address removed so that you cannot be recognised from it. (We will need to have a record of your name and address so that we can send you questionnaires and diaries – but this will be kept separate from any other details about you.)

We will need to tell your child's GP that you are taking part in this trial, and to let them know that you have given us permission to look at their medical records. But we will not tell your GP, or anyone else, anything that you say in the diaries or questionnaires, unless you ask us to.

What will happen to the results of the research study?

The results of the research study will go to the National Health Service so that they will know better how to treat children with tonsillitis. No one who reads the results will be able to identify your child. If you would like to know the results of the research study please say so when you fill in the consent form. We will send you a copy of the results at the end of the study – this will be in 2008.

Who can I contact for more information?

You can ask the nurse who gave you this sheet or the doctor you saw at the hospital for more information. Their names are at the bottom of this page. These are the best people to ask if you have any questions about treatments for sore throats or about your child's medical situation. Or, you can contact the NESSTAC study team at Newcastle University on 0191 222 8709 (their address is shown below). Please ask for Mary Dickinson, the project secretary.

Please do not contact the hospital staff if your child gets a sore throat – in this case the best person to contact is your own GP, just as you have done up to now.

For more information please contact:

Newcastle upon Tyne:
Professor Janet Wilson and Mr Sean Carrie

Liverpool: Mr Ray Clarke

Manchester: Mr Andrew Zarod

Bradford: Mr Christopher Raine

Glasgow: Mr Haytham Kubba

Mrs Mary Dickinson
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North of **E**ngland and **S**cotland **S**tudy of **T**onsillectomy
and **A**deno-tonsillectomy in **C**hildren

The Tonsil Follow-up Study Information for Children



How would you like
to take part in a
research study?

Before you decide, we want to tell you about the study and what taking part in it would mean for you. Please read this leaflet and talk to your parents or other people about it if you want to. Because the leaflet talks about medical treatments, you may not know some of the words. Just ask the nurse or doctor about anything that is not clear. They will be very happy to answer any questions you have.

Thank you for reading this.

What is the tonsil
follow-up study?



The tonsil study is trying to find out the best way of treating children who get lots of sore throats. Some

parents and children have agreed to take part in the main part of the tonsil study. In the main part of the tonsil study, children are put at random in either the "wait and see" group or the "tonsils out" group.

Other parents and children have decided that they would prefer not to take part in the main part of the study. This is fine – no one will be cross with them because of what they decided. However we would like to follow up some of these children too. This is so that we can see what happens normally – when parents and children together with their doctors decide what happens. This is what we are calling the tonsil follow-up study.

The only thing we want to do with the children taking part in the tonsil follow-up study is to find out about their treatment choices and the illnesses they get. Taking part in the tonsil follow-up study will make no difference at all to your treatment. You and your doctors and parents will be able to choose the treatment you prefer. Just like you would if you weren't taking part in any study.



Why have I been chosen?

We are asking all the children who were suitable for the main part of the tonsil study, but chose not to take part, to be in the tonsil follow-up study. We need to include up to 400 children in the tonsil follow-up study.



Do I have to take part?

No – you don't have to take part if you don't want to. Nobody will be cross with you if you say you don't want to take part. If you say yes now but change your mind later, that's OK too. But if you do take part you will be helping to answer an important question which is bothering doctors and nurses around the country.

What will happen if I agree to take part?



First, we will ask you to sign a "consent" form. This is to show that you are happy to be in the tonsil follow-up study. We will need to get some information about your sore throats from your doctor's records. The form asks you to say if this is OK. Please tell the nurse before you sign the form if you don't understand, or don't like something in this information sheet or the consent form.

You will then have the treatment that you and your parents and doctor decide is best for you.

We will ask you to answer some questions about your health. We will do this by giving you some questionnaires and a diary to fill in. The diary isn't like a diary where you write in sentences about what you did on holiday. In this one we just ask you to circle some numbers. The research nurse can show you the questionnaires and diaries now if you would like to see them. If you decide to take part in the study, the research nurse will show you how to fill in the questionnaires and diaries.

Are there any reasons why I might not want to take part?



The only downside to taking part is the time taken to fill in the questionnaires and diaries. There are no risks from taking part in the tonsil follow-up study.

Will I get anything out of taking part in the study?



You won't get any special treatment because you're taking part in the tonsil follow-up study. We hope that you will feel proud to be helping answer an important question about children's health. This will help us to treat children with sore throats and tonsillitis better in the future.

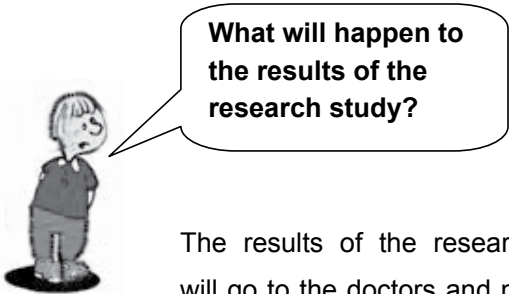
Will you tell anyone what I say?



We will keep all the information we collect about you private and confidential.

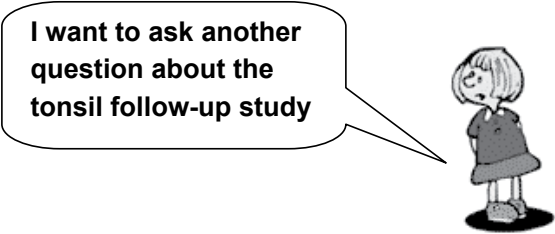
We will need to tell your family doctor that you are taking part in this study, and that you have said it is OK for us to look at your medical records. But we will not tell your family doctor, or anyone else, anything that you tell us, unless you ask us to.

The only time we might have to tell somebody about something you tell us, is if you tell us something that makes us very worried about you. But we would still try and check with you first before we told anyone else.



What will happen to the results of the research study?

The results of the research study will go to the doctors and nurses so that they will know better how to treat children with tonsillitis. If you'd like to know the results of the research study please tell us.



I want to ask another question about the tonsil follow-up study

Just ask the nurse or the doctor at the hospital. Their names are at the bottom of this page.

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Teenager Information Sheet

Follow-up study

Would you like to take part in a research study? Before you decide, we want to tell you about the study and what taking part in it would mean for you. Please read this leaflet and talk to your parents or other people about it if you want to. Ask the nurse or doctor about anything that is not clear. They will be very happy to answer any questions you have. Thank you for reading this.

What is the NESSTAC follow-up study?

The NESSTAC study is trying to find out the best way of treating children and teenagers who get lots of sore throats. Some people have agreed to take part in the NESSTAC randomised controlled trial. In this, children and teenagers are put at random in either the “wait and see” group or the “tonsils out” group.

Other people have decided that they would prefer not to take part in the NESSTAC randomised controlled trial. This is fine – no one will be annoyed with them because of what they decided. However we would like to follow up some of these children and teenagers too. This is so that we can see what happens normally – when parents and teenagers together with their doctors decide what happens. This is what we are calling the NESSTAC follow-up study.

The only thing we want to do with the children and teenagers taking part in the follow-up study is to find out about their treatment decisions and the illnesses they get. Taking part in the NESSTAC follow-up study will make no difference at all to the treatment you get. You and your doctors and parents will be able to choose the treatment you prefer. Just like you would if you weren't taking part in any study.



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Royal Hospital for Sick Children (Yorkhill)

Why have I been chosen?

We are asking all the children and teenagers who were suitable for the NESSTAC randomised controlled trial, but chose not to take part, to take part in the NESSTAC follow-up study. It is important that we have lots of teenagers as well as younger children. We need to include up to 400 children and teenagers altogether in the follow-up study.

Do I have to take part?

No – you don't have to take part if you don't want to. Nobody will be annoyed with you if you say that you don't want to take part. If you say yes now but change your mind later, that's OK too. But if you do take part you will be helping to answer an important question which is bothering doctors and nurses around the country.

What will happen if I agree to take part?

First, we will ask you to sign a consent form. This is to show that you are happy to be in the NESSTAC follow-up study. We will need to get some information about your sore throats from your doctor's records. The form asks you to say if this is OK. Please tell the nurse before you sign the form if you don't understand, or don't like, something in this information sheet or the consent form.

You will then have the treatment that you and your parents and doctor decide is best for you.

We will ask you to answer some questions about your health. We will do this by giving you some questionnaires and a diary to fill in. The diary isn't like a diary where you write in sentences about what you did on holiday. In this one we just ask you to circle some numbers. The research nurse can show you the questionnaires and diaries now if you would like to see them. If you decide to take part in the study, the research nurse will show you how to fill in the questionnaires and diaries.

Are there any reasons why I might not want to take part?

The only downside to taking part is the time taken to fill in the questionnaires and diaries. There are no risks from taking part in the NESSTAC follow-up study.

Will I get anything out of taking part in the study?

You won't get any special treatment because you're taking part in the NESSTAC follow-up study. We hope that you will feel proud to be helping answer an important question about children and teenagers' health. This will help us to treat children and teenagers with sore throats and tonsillitis better in the future.

Will you tell anyone what I say?

We will keep all the information we collect about you private and confidential.

We will need to tell your family doctor that you are taking part in this study, and that you have said it is OK for us to look at your medical records. But we will not tell your family doctor, or anyone else, anything that you tell us, unless you ask us to.

The only time we might have to tell somebody about something you tell us, is if you tell us something that makes us very worried about you. But we would still try and check with you first before we told anyone else.

What will happen to the results of the research study?

The results of the research study will go to the doctors and nurses so that they will know better how to treat children and teenagers with tonsillitis. If you'd like to know the results of the research study please tell us.

I want to ask another question about the NESSTAC study

Just ask the nurse or the doctor at the hospital. Their names are at the bottom of this page.

For more information please contact:

Newcastle upon Tyne:
Professor Janet Wilson and Mr Sean Carrie


Liverpool: Mr Ray Clarke

Manchester: Mr Andrew Zarod

Bradford: Mr Christopher Raine

Glasgow: Mr Haytham Kubba

Mrs Mary Dickinson
NESSTAC
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Newcastle University
21 Claremont Place
Newcastle upon Tyne
NE2 4AA

 0191 222 8709

NESSTAC

North of England and Scotland Study of Tonsillectomy and Adeno-tonsillectomy in Children



Parent Information Sheet

Follow-up study

You and your child are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

What is the NESSTAC follow-up study?

The NESSTAC study is measuring the effects of removing the tonsils of children with regular sore throats. Some parents and children have agreed to take part in the NESSTAC randomised controlled trial. This will compare surgical treatment (tonsillectomy) with medical treatment from GP and hospital doctors.

Other parents and children have decided that they would prefer not to take part in the randomised controlled trial. This is fine and will in no way affect the standard of care that they will receive. However we would like to follow up some of these children too. This will allow us to compare the trial results with what happens in the usual course of events, outside any trial. This is what we are calling the NESSTAC follow-up study.

The only thing we want to do with the children taking part in the follow-up study is to collect information about the treatment they receive and the illnesses they suffer from. Joining the follow-up study will make no difference whatsoever to the treatment you are offered.

Why has my child been chosen?

All children who are suitable for the NESSTAC randomised controlled trial but have chosen not to take part are being considered for the NESSTAC follow-up study. We need to include up to 400 children in the follow-up study.



Centre for Health Services Research
21 Claremont Place
Newcastle upon Tyne
NE2 4AA

The NHS logo, consisting of the letters 'NHS' in white on a dark grey background.

Newcastle upon Tyne Hospitals NHS Trust
Freeman Hospital

Royal Liverpool Children's NHS Trust
Alder Hey Children's Hospital

Manchester Children's Hospitals NHS Trust
Booth Hall Children's Hospital

Bradford Teaching Hospitals NHS Trust
Bradford Royal Infirmary

NHS Greater Glasgow
Royal Hospital for Sick Children (Yorkhill)

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you are still free to opt out at any time and without giving a reason (though it might help the researchers if you do give a reason). Your child will get the best possible care as a patient, no matter what you decide to do. Your doctor is not being paid to include you in the follow-up study.

What will happen if I agree to take part?

First, you will be asked to sign a consent form to show that you are happy to take part in the NESSTAC follow-up study. You will also be asked to sign to say that you are happy for a data collector to get some information about your child's sore throats from the GP's records, at the end of the study. If there is anything on the consent form, or in this information sheet, that you do not understand or agree with please tell the nurse before you sign the form. You will be given a copy of your signed consent form and of this information sheet to keep.

Your child will then have the treatment that you and your doctor decide is best for him or her. **The NESSTAC study will not influence the treatment that your child gets, in any way.**

You will be asked to complete 4 questionnaires over the next 2 years. These questionnaires will have questions about your child's health, and the impact of any illnesses they have on both you and your child. Some of these questions will be about the costs to you of your child's illnesses. There is also a simple health diary to complete. We estimate that each questionnaire should take no more than 15 minutes to complete. If your child is aged 8 or over then there will be separate questionnaires for them to fill in as well as a diary. We will post these out to you with a reply paid envelope for you to return them to us. The research nurse can show you the questionnaires and diaries now if you would like to see what they will involve. If you decide to take part in the study, the research nurse will show you how to complete the questionnaires and diaries. If you do not think you would be prepared to fill in these questionnaires and diaries then you should not agree to take part in the study.

What are the possible disadvantages and risks of taking part?

Apart from the time taken to fill in the questionnaires and diaries, there are no disadvantages or risks to you and your child from taking part in the NESSTAC follow-up study.

What are the possible benefits of taking part in the study?

There are no direct benefits to you and your child from taking part in the study. But you will be helping answer an important question about children's health. The aim of the study is to treat future children with sore throats and tonsillitis better.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital or the GP surgery will have your name and address removed so that you cannot be recognised from it. (We will need to have a record of your name and address so that we can send you questionnaires and diaries – but this will be kept separate from any other details about you.)

We will need to tell your GP that you have given us permission to look at your child's medical records. But we will not tell your GP, or anyone else, anything that you say in your questionnaires and diaries, unless you ask us to.

What will happen to the results of the research study?

The results of the research study will go to the National Health Service so that they will know better how to treat children with tonsillitis. No one who reads the results will be able to identify your child. If you would like to know the results of the research study please say so when you fill in the consent form. We will send you a copy of the results at the end of the study – this will be in 2008.

Who can I contact for more information?

You can ask the nurse who gave you this sheet or the doctor you saw at the hospital for more information. Their names are at the bottom of this page. These are the best people to ask if you have any questions about treatments for sore throats or about your child's medical situation. Or, you can contact the NESSTAC study team at Newcastle University on 0191 222 8709 (their address is shown below). Please ask for Mary Dickinson, the project secretary.

Please do not contact the hospital staff if your child gets a sore throat – in this case the best person to contact is your own GP, just as you have done up to now.

For more information please contact:

Newcastle upon Tyne:
Professor Janet Wilson and Mr Sean Carrie

Liverpool: Mr Ray Clarke

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