

What will happen if my child takes part?

Taking part in the study lasts for 2 days with a phone call on the 5th day. The nurse will visit you at the start and on the next 2 days. These visits will be somewhere to suit you, usually your own home. On the 5th day, the nurse will telephone you. The very first visit will be to talk through the study with you and will be in time for your child to be given the study medicines if still feverish. Until this meeting, you should carry on and treat your child's fever as you normally would or as advised by your GP. **You should not delay treatment unnecessarily.**

Once you have had the study explained and if you are happy to take part, your child will join one of three groups who will all be given a medicine to treat their fever. The treatment is different between the groups to allow us to see whether either medicine (paracetamol or ibuprofen) on its own or the two together work best.



The medicines

One group will all be given paracetamol and syrup that looks and tastes like ibuprofen but doesn't have the medicine in it (called a placebo).

A second group will all be given ibuprofen and syrup that looks and tastes like paracetamol but doesn't have the medicine in it (a placebo).

The third group will all be given paracetamol and ibuprofen (no placebos).

All medicines are sugar and gluten free and every child will be given at least one medicine to treat fever. A computer program will randomly decide the treatment given to your child.

The amount of medicine given will be based on your child's weight. For paracetamol, this will be 15mg per kg body weight given up to 4 times daily and for ibuprofen, this will be 10mg/kg up to 3 times daily. These may be slightly different to the doses you normally give but are the recommended licensed doses.

Looking at how your child recovers

To compare how well the children in the three groups get on, we will measure their temperatures using a little box (temperature data logger) they wear in a vest for 24 hours (1 day). We will also ask you to keep a careful note for the first 48 hours of how well they have been (on a special card) and also to measure their temperature for us occasionally so that

we can check the box is working properly and can see how they do when it has been taken off.

The **PITCH** nurse will explain everything again and answer any questions you have during your time in the study. We will not need to do any other tests.

What will I have to do?

You will be asked to give the study medicines for the first 2 days. During these 2 days, we will ask that you do not use any other medicines that you may have at home for fever or pain. Other medicines your child normally receives should be continued as usual, **so long as they do not contain paracetamol or ibuprofen.** We will ask you to meet the nurse at arranged times after the 1st and 2nd days in the study and keep the record of how well your child recovers. On the 5th day, we will telephone you and ask about the cost to you and the Health Service of looking after your child through their illness.

What are the alternative treatments?

There are no other medicines licensed in the UK for the treatment of fever in children, but there are other non-medicine treatments. We will give you an advice sheet of the other things you can do to help control your child's temperature like giving extra drinks and loosening his or her clothing.

What are the side effects of the study medicines?

The study medicines are not new and are available to buy at the chemists. When taken at the right dose, they are safe.

The doctor or nurse you see will check it is safe for your child to use them. As with any medicine, the study medicines can have side effects.

For paracetamol, side effects are rare and mild. Rarely, the following can happen: skin rashes or other sorts of allergy, bruising or bleeding.

For ibuprofen, side effects are uncommon. The most common are a mild laxative effect and stomach discomfort. Rare side effects are nausea (feeling sick), stomach pains, a rash, itching or worsening of asthma, unexplained wheezing or shortness of breath. Very rarely, facial swelling (get medical help immediately), black, tarry stools, bleeding from the stomach or bowels, skin peeling or easy bruising may happen.

If your child experiences these or any other symptoms, you should contact your GP in the usual way, telling him/her that your child is in the **PITCH** study. Where necessary, your GP will be able to find out which medicine/s your child has received.

What are the possible disadvantages and risks of taking part?

Taking part in this study is **very unlikely** to put you or your child at greater risk than if you chose not to take part because:

- Your child will be given treatments already widely used by parents
- Your doctor or nurse will have checked that the study medicines are safe for your child
- You will not be asked for any sensitive information.
- All the children will be given at least one medicine which treats fever.

The first visit may last for up to 1 hour, and the next two visits between 30 and 45 minutes (less than an hour). The telephone call on day 5 will last for up to 15 minutes. We wish to keep any demands on your family to a minimum and will be happy to arrange for the visits to be in your own home.

What are the possible advantages of taking part?

The study treatment is the same or similar to what you would normally be prescribed. We hope that the results from the study will help inform us of the best way to treat children with fever in the future.

What if something goes wrong?

It is unlikely that taking part in the study will harm your child, but if harm does result from this research, there are no special compensation arrangements.

If for any reason you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should contact the Study Coordinator Ceire Costelloe, or the normal National Health Service complaints system can be used. If you are harmed due to someone's negligence, you may have grounds for a legal action but you may have to pay for it yourself.

Will my taking part in this study be kept confidential?

If you agree to take part in the study, your child's medical records may be inspected by authorised staff from the Department of Health or from the research team at Bristol University or from other regulatory authorities. This may be done to check the study is being carried out properly. The research team will only use any personal information for the purposes of the study. (All information will be protected according to the UK Data Protection Act 1998). We will let your GP know you are taking part but any information to do with the study will be kept strictly confidential. Any reports resulting from the study will have your name and address removed so that you or your child cannot be identified.

What will happen to the results of the research study?

We plan to publish the results of this study by the end of 2007. We will ask the GP practices and medical centres involved to display a summary of our findings and, if you are interested to know more, you will be able to ask your GP practice/medical centre for more information. You can also contact the **PITCH** study team directly.

Who is organising and funding this research?

The study is being organised by a team of researchers from the University of Bristol, led by Dr Alastair Hay. The study is supported by a grant from the National Coordinating Centre for Health Technology Assessment (part of the NHS) and is regulated and monitored by the Department of Health.

Who has reviewed this study?

This study has been approved by the Bath Local Research Ethics Committee.

Who do I contact for further information?

In most cases, the research nurse will be contacting you. If they don't, or you have any other questions or decide you would rather not take part, please contact:

Susan Doohan, or Ceire Costelloe.

Their telephone numbers and an email address are given on this leaflet.

You will be given copies of this information sheet and a signed consent form to keep.

What do I do now?

Please continue to treat your child as advised by your doctor/nurse until the **PITCH** study team contact you. If at any time you become concerned about your child's condition, **do not wait for the PITCH team to contact you**, but contact NHS Direct (0845 46 47) or your GP in the usual way.

Thank you for considering taking part in this research.

Ceire Costelloe

PITCH study coordinator on behalf of the **PITCH** study investigators.

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With University of the West of England (UWE) and the University of Bath

PITCH



Paracetamol and Ibuprofen for the Treatment of fever in Childhood

PARENT INFORMATION SHEET

What is the PITCH study about?

Fever is a common problem in children and medicines like paracetamol (in Disprol[®] and Calpol[®]) and ibuprofen (in Nurofen[®] or Calprofen[®]) are often used to treat the fever, though we don't know which works best. We are all concerned when children become feverish, but no one knows which medicines work best. Together we would like to try to find this out.

Why have we been invited to take part?

You are being invited because you contacted the doctor or nurse (or NHS Direct) today about a young child with a fever and agreed to let us contact you.

Do I have to take part?

It is for you to decide whether or not you and your child take part. If you do take part you will be asked to sign a consent form but you will still be free to change your mind and leave the study at any time and without giving a reason. The standard of care or treatment you and your child receive will not be affected in any way if you decide to leave the study or if you decide not to take part.