



### *The purpose of the study?*

Temperatures (fevers) are a common problem in children. Medicines such as paracetamol (in Disprol or Calpol) and ibuprofen (Nurofen or Calprofen) are often used to treat a temperature, though we do not know which medicine works best. We are all concerned when children become feverish, but no one knows how best to treat them. Together, we would like to find out which medicines works best. We hope that around 300 children in the Bristol area will take part in the **PITCH** study over its two-year course.

### *What would happen if my child took part?*

The study lasts for 2 days with a phone call on the 5<sup>th</sup> day. A **PITCH** nurse would visit you at the start and on the next two days. These visits would be somewhere convenient to you, usually your own home. On the 5<sup>th</sup> day the nurse would telephone you. The very first visit would be to talk through the study with you and would be in time for your child to be given the study medicines if s/he was still feverish. Until this meeting, you would continue to treat your child's fever as you normally would. **You would not be asked to delay treatment unnecessarily.**

Once you had the study explained and felt happy to take part, your child would join one of three groups who would all be given at least one medicine to treat their fever.



### *The medicines*

All children receive at least one active medicine. One group would all be given paracetamol and syrup that looks and tastes like ibuprofen but doesn't have the medicine in it (called a placebo).

The second group would all be given ibuprofen and placebo paracetamol syrup.

The third group would all be given paracetamol and ibuprofen (no placebos). A computer will decide at random the group your child will be put in.

All medicines are sugar and gluten free and every child would be given at least one medicine to treat the fever and discomfort. The amount of medicine given would be calculated according to your child's weight. This may be slightly different to the dose you normally give.

### *Looking at how your child recovers*

To compare how well the children in the three groups get on, we would measure their temperature using a special thermometer that they wear in a vest for 24 hours. We would also ask you to keep a note for 48 hours of how well they are recovering (on a diary card) and also to measure their temperature for us occasionally. This is to check the special thermometer is working properly and see how they do when it is taken off. The **PITCH** nurse would explain everything clearly at the time and be available to answer any questions you have during your time in the study.



### *What would I have to do?*

You would be asked to give the study medicines for the first 2 days. During these 2 days, we would ask that you do not use any other medicines that you may have at home for fever or pain. Other medication your child normally takes would be continued as normal, **so long as they do not contain paracetamol or ibuprofen.** We would ask you to meet the study nurse at the arranged times on days 1 and 2, keep the special thermometer in place for up to the first 24 hours and to keep a diary of how well your child recovers.

### *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-medicinal treatments. We would give you an advice sheet of the other things you can do to help control your child's temperature, e.g. giving extra fluids and loosening his/her clothing.

### *I'm interested, but do I have to take part?*

It is up to you to decide whether or not you and your child take part in the study. If you decided to take part, you would still be free to 'change your mind' and leave the study at any time and without giving a reason.

### *What are the side effects of the study medicines?*

The study medicines are not new and are widely available to parents to buy at the chemist. When taken at the correct dose, they are safe. The **PITCH** nurse would check it is safe for your child to use them. As with any medicine, the study medicines can give side effects, but these are rare and mild.

If your child experienced any side effects or any new symptoms, you should contact your GP in the usual way, telling him/her that your child was in the **PITCH** study. If necessary, your GP would be able to find out which medicine/s your child had 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 would be receiving treatments already widely used by parents
- The **PITCH** nurse would have checked that the study medicines are safe for your child
- You would not be asked for any sensitive information
- All children will be given at least one medicine which would help their fever.

The first visit will last for up to one hour and the next two visits between 30 and 40 minutes. We wish to keep any demands to your family to a minimum and would 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 treatment option for children with fever in the future.

### *What will happen to the results of the research study?*

We plan to publish the results of this study in a medical journal by the end of 2007. We will ask your practice to display a summary of the results and, if you are interested to know more about the results, you will be able to ask your practice for further information. Alternatively, if you are interested to know more, you can 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 NHS and is monitored and regulated by the Department of Health.

### *Who has reviewed this study?*

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

### *What do I do now?*

At this stage we are asking only that you to consider whether or not you would participate if your child developed a fever in the next year. You do not need to do anything else at this stage. If you have any questions you can contact the study secretary on: 0117 331 0811.

### *How do I take part?*

If your child develops a fever, there are 2 ways in which you and your child can be referred to the study team:

1. If you sought medical advice through either your GP/Nurse, the Walk-in Centre (Knowle West), NHS Direct, or the Children's Hospital Emergency Department, you may be invited to take part, or you can ask to be referred to the study.
2. Although not designed to be instead of seeing your doctor, if you feel that your child's fever or illness is not severe enough for you to seek medical advice, you can contact the study team directly on:


**0117 331 0811**

*Thank you for considering taking part in this research.*

**Niamh Redmond**

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**Bristol North Primary Care Trust  
Bristol South and West Primary Care Trust  
South Gloucestershire Primary Care Trust  
United Bristol Healthcare NHS Trust**



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

**FEVER?  
?PITCH**

**Paracetamol and Ibuprofen for the  
Treatment of fever in Childhood**



### ***Information about the study***

This leaflet is to let you know that if your child is aged 6 months to less than 6 years of age and develops an illness with a high temperature, you may wish to consider taking part in the PITCH study. Deciding whether or not to take part might be difficult when your child is ill, so we wanted to give you the chance to consider the invitation now.