



Paracetamol and Ibuprofen for the Treatment of fever in Childhood

PITCH trial remote & local recruitment v1.11

- 1. CHILD CURRENTLY HOT OR RECEIVED ANTIPYRETICS FOR FEVER IN THE LAST 8 HOURS?
- 2. AGED BETWEEN 6 MONTHS AND LESS THAN 6 YEARS?

IF YOU CAN ANSWER **YES** TO THESE TWO QUESTIONS, THEN COMPLETE THE **PITCH** PAPERWORK AND

FAX TO (0117) 954 6647 ANYTIME

PLEASE ADVISE PARENTS THAT:

- THE PITCH RESEARCH NURSE WILL CONTACT THEM BY TELEPHONE WITHIN 24 HOURS.
- UNTIL THEN, ANTIPYRETIC TREATMENT SHOULD CONTINUE AS PER YOUR ADVICE.
- CONCERNS REGARDING THE CHILD'S MEDICAL CONDITION SHOULD BE DIRECTED TO NHS DIRECT OR THE CHILD'S GP.

THANK YOU

PITCH trial prescription Trial number: ISRCTN 26362730

Child's Name:

Child's Date of Birth: ____/20___

I confirm that

1. This child meets the eligibility criteria:

- Is aged between 6 months and less than 6 years
- Has a fever now **OR** has been given ibuprofen or paracetamol for fever in the previous eight hours
- Does not require hospital admission for diagnosis or treatment of the underlying cause for the fever at the present time

2. The child:

• Has no known exclusion criteria

(exclusions are (i) dehydration, (ii) requires hospital admission or (iii) known to have epilepsy (or other chronic neurological disease), pulmonary disease (except for asthma, this is NOT an exclusion), liver, renal or cardiac disease, previous peptic ulceration or bleeding, an allergy or intolerance to paracetamol or ibuprofen).

- Has no known contraindication to treatment with paracetamol and/or ibuprofen
- Is not taking any regular medication that might adversely interact with paracetamol or ibuprofen (see Appendix 1, BNF for details).
- If child is NOT eligible for the study please give reason______

Please sign below to confirm that, if the parent consents to randomisation, you are happy for the following medicines to be given to the above patient by the PITCH study team

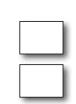
| Medicine | Dose | Quantity to be given |
|-------------------------|--|----------------------|
| Paracetamol | DAY 1: Please give 15mg/kg every 4 to 6 hours | 140ml |
| 120mg/5ml SF | REGULARLY maximum of 4 doses in 24 hours. | |
| suspension (or placebo) | DAY 2: Please give 15mg/kg every 4 to 6 hours | |
| | AS NEEDED maximum of 4 doses in 24 hours. | |
| AND | | |
| Ibuprofen 100mg/5ml | DAY 1: Please give 10mg/kg every 6 to 8 hours | 100ml |
| SF suspension (or | REGULARLY maximum of 3 doses in 24 hours. | |
| placebo) | DAY 2: Please give 10mg/kg every 6 to 8 hours | |
| | AS NEEDED maximum of 3 doses in 24 hours. | |

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|----------|-------|
| | |

Name of Doctor (BLOCK CAPITALS or PRACTICE STAMP) Date

Signature

PLEASE TURN OVER AND COMPLETE THE CLINICAL DETAILS





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Please initial the box

QUESTIONS ABOUT THE CHILD'S FEVER AND TREATMENT.

| 1. If measured (parent or clinician), please record the child's most recent temperature (°C) and time: NB . A measured temperature is NOT a requirement for referral to the PITCH team | Temp (°C)Time (24 hour clock) | | | | |
|--|-----------------------------------|--|--|--|--|
| 2. Please explain how this was assessed (tick one box of | only) | | | | |
| By touch (e.g. hand on forehead) . | Electronic axillary thermometer | | | | |
| Tympanic thermometer | Other 4 | | | | |
| If other please explain: | | | | | |
| 3. How would you classify the cause of this child's few | er? | | | | |
| Upper respiratory tract infection | Lower respiratory tract infection | | | | |
| Otitis media | Tonsillitis | | | | |
| Infective exacerbation of asthma. | Pneumonia (clinical diagnosis) . | | | | |
| Gastroenteritis | Non-specific viral illness . | | | | |
| Other 9 If other please specify: | | | | | |
| 4. How would you rate the severity of the underlying i | illness? | | | | |
| Minor | | | | | |
| termediate \square^2 (E.g. asked to come back if not improving) | | | | | |
| oderate | | | | | |
| 5. Have you prescribed an antibiotic | Yes No | | | | |
| | | | | | |
| 6. Please list the names (only) of all new medication (e.g. antibiotics, inhalers) you have advised or prescribed: | | | | | |
| | Yes No | | | | |
| 7. Is the child receiving regular medication? | | | | | |
| 8. Please list the names (only) of all medication the | | | | | |
| | | | | | |
| 9. Please indicate which antipyretic medicines you would ordinarily have advised this child to use: P = paracetamol, I = ibuprofen only, P+I = both | P I P+I | | | | |
| 8. Please list the names (only) of all medication the child usually receives: 9. Please indicate which antipyretic medicines you would ordinarily have advised this child to use: | | | | | |

Thank you. Please ask the parent to sign the form on the next page and then ask your secretary to fax the **WHOLE FORM** to the **PITCH** research team as soon as possible to (0117) 954 6647.

I agree that details of my child's current episode of illness, treatment and my contact details given below can be given (in person or by telephone or secure fax) to the researchers carrying out the **PITCH** trial. This will enable them to contact me and explain the trial in more detail so that I can then decide whether or not to take part.

| (BLOCK CAPITALS | PLEASE) | | | | |
|-----------------------------|----------------|-----------------------|---------|--|--|
| Child's name: | | | | | |
| Parent/Guardian's Name: | | | | | |
| | Mr/Mrs/Miss/Ms | Forename | Surname | | |
| Address: | | | | | |
| | | | | | |
| | | | | | |
| Postcode: | | | | | |
| Main contact number: | | | | | |
| Alternative contact number: | | | | | |
| | | | /20 | | |
| | Signatu | re of parent/guardian | Date | | |

Signature of parent/guardian