

# A randomised controlled trial of the combined use of paracetamol and ibuprofen to treat febrile children

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/04/2012	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr MDS Erlewyn-Lajeunesse

### Contact details

C/O Research & Effectiveness Department  
Level 1, The Old Building  
Bristol Royal Infirmary  
Malborough Street  
Bristol  
United Kingdom  
BS2 8HW  
+44 (0)117 928 3473  
[r&eoffice@ubht.swest.nhs.uk](mailto:r&eoffice@ubht.swest.nhs.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0264160475

# Study information

## Scientific Title

### Study objectives

To ascertain whether using paracetamol and ibuprofen in combination is better than using either alone when treating children with fever in the setting of an emergency department.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Fever

### Interventions

Unblinded but RCT. Children presenting at the children's emergency department with fever will be invited to take part. Those with a temperature greater than or equal to 38.0 degrees C will be enrolled subject to consent.

Subjects will be allocated at random to one of three treatment arms:

1. Ibuprofen alone (5mg/kg)
2. Paracetamol alone (15 mg/kg)
3. Ibuprofen (5mg/kg) & Paracetamol (15 mg/kg)

Subjects will receive a single treatment. Temperature will be recorded at dosage, 1 hour later and if still in the department, 2 hours later.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

The child's temperature one hour after study antipyretics

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/10/2004

**Completion date**

04/04/2005

**Eligibility****Key inclusion criteria**

Children presenting in the BRI children's emergency department with fever. Inclusion criteria:

1. Age 6 months - 16 years
2. Children with a temperature of 38.0 degrees C or more will be eligible

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

120

**Key exclusion criteria**

1. Those admitted directly to resuscitation by ambulance or those transferred there following initial clinical assessment
2. Those eligible for recruitment in any other study running concurrently or those who have been

recruited to a simultaneous study of children's fever

3. Prior administration that will interfere with randomisation: paracetamol within the last six hours or ibuprofen within the last six hours

4. Allergy to either study drug

5. Likely dehydration, cellulitis or skin infection, concomitant warfarin or heparin, chronic illness likely to interfere with drug metabolism (kidney or liver disease), immunosuppression, HIV+, concomitant chemo or radiotherapy, organ or bone marrow transplant recipient, immunosuppressive therapy in the last three months

**Date of first enrolment**

01/10/2004

**Date of final enrolment**

04/04/2005

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**C/O Research & Effectiveness Department**

Bristol

United Kingdom

BS2 8HW

## **Sponsor information**

**Organisation**

Record Provided by the NHSTCT Register - 2005 Update - Department of Health (UK)

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

**Funder type**

Government

**Funder Name**

United Bristol Healthcare NHS Trust (UK)

**Funder Name**

NHS R&D Support Funding (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2006		Yes	No