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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 30/09/2005 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 30/09/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 10/04/2012 | Signs and Symptoms | |

**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

## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Not Specified

## 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(s)
The child's temperature one hour after study antipyretics

## Key secondary outcome(s))
Not provided at time of registration

## 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
6 months

### Upper age limit
16 years

### Sex
All

### 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
United Kingdom

England

**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)

# Funder(s)

**Funder type**
Government

**Funder Name**
United Bristol Healthcare NHS Trust (UK)

**Funder Name**
NHS R&D Support Funding (UK)

# Results and Publications

**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? |
|---|---|---|---|---|---|
| Results article | results | 01/05/2006 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |