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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

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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?
Results article	results	01/05/2006		Yes	No