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Ibuprofen and paracetamol in combination and separately for fever in pre-school children presenting to primary care: a randomised controlled trial.

Submission date 24/06/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 24/06/2004	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 25/08/2009	**Condition category** Signs and Symptoms	[_] Individual participant data

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
HTA 03/09/01

Study information

Scientific Title

Acronym
PITCH (Paracetamol and Ibuprofen for the Treatment of fever in CHildhood)

Study objectives
Aim: This trial will establish whether paracetamol and ibuprofen combined confers advantages over either agent alone in the relief of fever and its associated symptoms in pre-school children presenting to primary care.
Objectives:
1. To establish the relative clinical effectiveness of paracetamol alone, ibuprofen alone or paracetamol and ibuprofen for fever clearance in the first four hours post randomisation in children aged between 6 months and 5 years presenting to primary care with fever
2. To assess the relative clinical effectiveness of paracetamol alone, ibuprofen alone or paracetamol and ibuprofen for the relief of fever associated discomfort during the period 24 to 48 hours post randomisation
3. To use qualitative methods to optimise the overall trial process and explore parents' and clinicians' beliefs about the use, effectiveness and side effects of ibuprofen and paracetamol
4. To perform an economic evaluation from the perspective of the NHS
comparing the cost and benefits of each treatment
Design: Three-arm, placebo controlled trial with automated telephone randomisation at the level of the individual.
Recruitment: Research nurses will support recruitment from 20 GP surgeries, three GP cooperatives, one WIC and one Children's Emergency Department in the Bristol area.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Three-arm, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Please note that, as of 14 January 2008, the anticipated start and end dates of this trial have been updated from 1 July 2004 and 31 December 2006 to 1 December 2004 and 30 November 2007, respectively.

Interventions:
Up to 48 hours use of the study medicines, given at doses and times according to the British National Formulary (BNF) or Medicines for Children recommendations. All parents will receive two medicines, of which at least one will be active.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ibuprofen. paracetamol

Primary outcome measure
1. Fever clearance in the first four hours (data logger)
2. 48-hour discomfort score (parent symptom score)

Secondary outcome measures
We will examine the time under fever threshold first 24 hours, adverse events and departures from protocol, the pattern of discomfort scores between 4 and 48 hours, the number of night-time doses administered, other symptoms and the NHS costs associated with the discomfort scores at 48 hours and 5 days.

Overall study start date
01/12/2004

Completion date
30/11/2007

Eligibility

Key inclusion criteria
Previously well children aged >6 months and <5 years presenting to primary care with a temperature at least 38°C.

Participant type(s)

Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
5 Years

Sex
Both

Target number of participants
831

Key exclusion criteria
Excluding children with epilepsy or known contraindications to the study medicines.

Date of first enrolment
01/12/2004

Date of final enrolment
30/11/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Primary Health Care
Bristol
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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	02/09/2008		Yes	No
Other publications	economic evaluation	09/09/2008		Yes	No
Other publications	health technology assessment	01/05/2009		Yes	No
Other publications		11/08/2009		Yes	No