

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	☒ Prospectively registered ☐ Protocol
Registration date 24/06/2004	Overall study status Completed	☐ Statistical analysis plan ☒ 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

Contact name

Dr Alastair Hay

Contact details

Academic Unit of Primary Health Care
Department of Community Based Medicine
Cotham House
Cotham Hill
Bristol
United Kingdom
BS6 6JL
+44 (0)117 954 6632/6694
alastair.hay@bristol.ac.uk

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Three-arm, placebo controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Months

Upper age limit

5 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Academic Unit of Primary Health Care

Bristol

United Kingdom

BS6 6JL

Sponsor information**Organisation**

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)**Funder type**

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	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