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A Pragmatic trial of Ibuprofen, Paracetamol and Steam

Submission date	Recruitment status	[_] Prospectively registered
14/01/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/06/2014	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-005740-83

Protocol serial number
Protocol 4

Study information

Scientific Title
A pragmatic randomised trial of ibuprofen, paracetamol, steam and delayed prescribing for patients with respiratory tract infections in Primary Care

Acronym
PIPS

Study objectives
To assess, in a primary care setting, in patients with respiratory tract infection (RTI), whether:
1. There is a difference in the effectiveness between three different antipyretic regimes: ibuprofen treatment, paracetamol treatment and combined ibuprofen and paracetamol treatment
2. Regular antipyretic dosing gives significantly better symptom and temperature control than 'as required' dosing
3. Regular inhalation with steam further improves symptom control
4. There are any differences in antibiotic use and acceptability according to different methods of delaying antibiotic use

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire REC (A) gave approval on the 12th January 2007 (ref: 06/Q1702/154)

Primary study design
Interventional

Study design
3 x 2 x 2 randomised factorial controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory tract infection

Interventions
Patients will be randomised to receive one of three kinds of medication advice, one of two kinds of dosing advice and one of two kinds of steam advice.

1. Medication advice:
1.1. Paracetamol: participants will be advised to use paracetamol as their only antipyretic medication
1.2. Ibuprofen: participants will be advised to use ibuprofen as their only antipyretic medication
1.3. Combined paracetamol and ibuprofen: participants will be advised to use paracetamol and ibuprofen

2. Dosing advice:
2.1. Regular dosing: advice to take the medication(s) four times per day (irrespective of whether symptoms or fever have returned)

2.2. As required dosing: advice to take medication(s) as required by symptoms up to a maximum of four doses per day

3. Steam Advice:
3.1. Steam: subjects will be asked to inhale steam for 5 minutes, three times per day. Adults will be instructed to place a towel over their head over a bowl of recently boiled water. Children will be instructed to sit in a steamy room (made steamy by running a hot shower, or boiling a kettle in the room). Participants will receive written and verbal instructions at the beginning of the study.
3.2. No Steam: subjects will be asked not to use steam inhalation

Delayed prescription:
1. Patient led: the patient is given antibiotics and asked to wait to use them
2. Post-dating: the patient is given antibiotics, but post-dated
3. Collection: instructions to wait but can request antibiotics from front desk
4. Recontact/phone: patient is asked to contact/phone the surgery to leave message for doctor /nurse regarding a request for antibiotics, and able to come to reception

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Mean symptom severity during the first 3 days (as measured by symptom diary).

Key secondary outcome(s)
1. Side effects: the symptom diary will allow documentation of adverse events (e.g. rash, diarrhoea, vomiting, abdominal pain)
2. Health service resource use: the diary will document contacts with the health service - including NHS direct, the GP surgery and, secondary care - and any prescribed medication. The notes will be reviewed to confirm prescribed medication and contact with primary and secondary care.
3. Axillary temperature: axillary temperature will be measured by tempadot thermometer twice daily for three days

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Aged 3 years and over, either sex
2. Presenting to a General Practitioner (GP) or nurse with an RTI diagnosed by the health professional (acute cold, influenza, sore throat, otitis media, sinusitis, croup, or lower respiratory tract infection)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Active or previous peptic ulceration
2. Hypersensitivity to aspirin ibuprofen or paracetamol
3. Inability to measure temperature or complete outcome measures (e.g. parents visually impaired, psychosis, severely depressed)
4. Patients requiring hospital admission (e.g. suspected meningitis, severe pneumonia, epiglottitis, Kawasaki's disease, etc.)
5. Patients with known immune deficiency (where the course of illness and symptomatic response might be modified)
6. Pregnancy or breastfeeding

Date of first enrolment
01/02/2009

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Primary Medical Care
Southampton
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Sponsor information

Organisation

University of Southampton (UK)

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) programme: PRIME Programme Grant (ref: RP-PG-0407-10098)

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	25/10/2013		Yes	No
Results article	results	06/03/2014		Yes	No