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A Pragmatic trial of Ibuprofen, Paracetamol and Steam

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

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
2006-005740-83

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol 4; 2006-005740-83

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)

Study design
3 x 2 x 2 randomised factorial controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
Mean symptom severity during the first 3 days (as measured by symptom diary).

Secondary outcome measures
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

Overall study start date
01/02/2009

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

Age group
Other

Sex
Both

Target number of participants
400 - 504

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
England

United Kingdom

Study participating centre
Primary Medical Care
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
c/o Martina Prude
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Sponsor type
University/education

Website
http://www.soton.ac.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

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