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Parent Initiated Prednisolone in Asthma (PIPA)

Submission date 22/02/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/05/2005	**Overall study status** Completed	
Last Edited 03/03/2010	**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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title
Parent Initiated Prednisolone in Asthma (PIPA): a randomised, placebo-controlled, crossover trial

Acronym
PIPA

Study objectives
Parent initiated prednisolone, when compared with placebo, in the setting of an episode of acute asthma is associated with a reduction in the mean asthma daytime symptom score

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo controlled crossover group 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
Asthma

Interventions
A short course of parent initiated oral prednisolone or placebo, administered as a single daily dose of 1 mg per kg in 10 mg brackets to a maximum of 50 mg daily.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prednisolone

Primary outcome measure

The mean 7-day asthma daytime symptom score.

Secondary outcome measures
1. Nocturnal symptom scores
2. Asthma free days
3. Days of school missed
4. Days of parental work missed
5. Unscheduled medical review due to acute asthma
6. Use of the participant's regular reliever medication
7. Prescription of a corticosteroid by the participant's physician for an asthma exacerbation
8. Adverse effects (including growth and behavioural changes)

Overall study start date
28/02/2005

Completion date
28/02/2007

Eligibility

Key inclusion criteria
1. Age: 5 to 11 years old
2. Definition of asthma: a history of recurrent episodes of bronchodilator responsive wheeze. This will be determined in each case by the principal investigator.
3. Asthma severity: four or more acute asthma exacerbations in the preceding 12 months. Asthma exacerbations will be defined as a subjective worsening of lung function that failed to respond to appropriate doses of 'reliever' medication within a 6 hour period.

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
308

Key exclusion criteria
1. Receiving systemic steroids daily or on alternate days
2. Chronic disease, other than asthma, that affects pulmonary function
3. Insulin dependent diabetes mellitus

Date of first enrolment
28/02/2005

Date of final enrolment
28/02/2007

Locations

Countries of recruitment
Australia

Study participating centre
Geelong Hospital
Geelong
Australia
3220

Sponsor information

Organisation
Murdoch Children's Research Institute (Australia)

Sponsor details
10th Floor
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Sponsor type
Research organisation

ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Charity

Funder Name
The Jack Brockhoff Foundation (Australia)

Funder Name
The Murdoch Children's Research Institute (Australia)

Funder Name
The Percy Baxter Foundation (Australia)

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	01/03/2010		Yes	No