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Is a single dose of steroids no worse than multiple doses in treating acute asthma episodes in children?

Submission date 27/04/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/06/2010	**Overall study status** Completed	
Last Edited 28/05/2020	**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

Clinical Trials Information System (CTIS)
2010-022001-18

ClinicalTrials.gov (NCT)
NCT03698630

Protocol serial number
N/A

Study information

Scientific Title
A randomised trial of single dose oral dexamethasone versus multi-dose prednisolone in the treatment of acute exacerbations of asthma in children who attend the Emergency Department

Study objectives
Asthma is a major cause of paediatric morbidity and mortality. In acute exacerbations of asthma, corticosteroids reduce relapses, subsequent hospital admission and the need for beta-2 agonist therapy. The earlier corticosteroids are administered in an acute episode, the better the clinical outcome. In the 2008 British Guidelines on the Management of Asthma, the British Thoracic Society (BTS) recommends commencing oral prednisolone early for children presenting with exacerbations of asthma and if discharged, continuing treatment for up to three days.

Prednisolone is relatively short acting with a half-life of 12 to 36 hours, requiring daily dosing. Outpatient steroid therapy is effective once compliance is assured. However, many factors impact on patient compliance with medication. One study found that at least 7% of children seen in a paediatric ED never have their prescriptions filled. Prolonged treatment course, vomiting and in particular a bitter taste may reduce patient compliance with prednisolone. If effective, a single dose of corticosteroid would remove the problem of poor compliance and therefore reduce morbidity and the risk of relapse.

Dexamethasone is a long-acting glucocorticoid with a half-life of 36 to 72 hours. It has been used safely in children with croup and bacterial meningitis, but is not specifically mentioned in the British Guideline on the Management of Asthma in children. It is well absorbed both orally and parenterally. Whereas intramuscular dexamethasone is invasive but ensures compliance, a single dose of oral dexamethasone would negate the need for an injection and retain the advantage of ensuring compliance.

The proposed trial will examine whether a single dose of oral dexamethasone phosphate (0.3 mg /kg) is non-inferior to prednisolone (1 mg/kg/day for 3 days) in the treatment of exacerbations of asthma of all levels of severity in children who attend the ED. This dosing regime is more reflective of current prescribing practices in paediatric emergency medicine in the UK and Ireland and also in Australasia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Our Lady's Children's Hospital, pending as of 27/04/2010

Study design
Single centre randomised double-blind non-inferiority clinical trial

Primary study design
Interventional

Study type(s)

Treatment

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

Interventions
Dexamethasone phosphate 0.3 mg/kg orally (PO) followed by one placebo dose daily for 2 days (3 doses in total) or prednisolone 1 mg/kg/day PO for 3 days.

Dexamethasone is licensed for use in the Republic of Ireland in a liquid or tablet form. The liquid preparation is available as a 2 mg/5 ml solution with a 150 ml bottle costing 80.18. The tablet preparation is available as a crushable 2 mg tablet costing 14.96 for a 100-tab pack. Prednisolone is available as dispersible 5 mg tablets costing 7.85 for a 20-tablet pack.

It is estimated that the study duration will be approximately 18 months.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Dexamethasone phosphate, prednisolone

Primary outcome(s)
Exacerbations of asthma, as measured by the Pediatric Respiratory Assessment Measure (PRAM), measured at enrolment, pre-ED discharge (4 hours) and at 4 days.

Key secondary outcome(s))
1. Relapse rates, measured at 4 and 14 days
2. Treatment cost

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Aged 2 - 16 years, either sex
2. Presentation with acute asthma, defined as:
2.1. At least two previous episodes of beta-2-agonist responsive wheeze in a child 2 years of age or over
2.2. A prior diagnosis of asthma, made by a paediatrician, or clinician of comparable experience
3. Present to the ED of Our Ladys Childrens Hospital, Crumlin (OLCHC), Dublin, Ireland

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Child

Lower age limit
2 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. Less than 2 years old or over 16 years
2. Previous enrolment in the study
3. Critical or life threatening asthma
4. Known tuberculosis (TB) exposure
5. Active varicella or herpes simplex infection
6. History of acute allergic reaction
7. Documented concurrent infection with respiratory syncytial virus (RSV)
8. Fever greater than 39.5°C
9. Use of oral corticosteroids or admission for asthma in the previous 4 weeks
10. Concurrent stridor
11. Possible intrathoracic foreign body
12. Significant co-morbid disease, i.e., lung, cardiac, immune, liver, endocrine, neurological or psychiatric

Date of first enrolment
01/07/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Ireland

Study participating centre
Paediatric Emergency Research Unit
Dublin
Ireland
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Sponsor information

Organisation
National Children’s Research Centre

ROR
https://ror.org/02typaz40

Funder(s)

Funder type
Research organisation

Funder Name
National Children's Research Centre

Alternative Name(s)
NCRC

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Ireland

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?
Protocol article	protocol	21/08/2012		Yes	No
Basic results			28/05/2020	No	No