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A comparison of intravenous salbutamol and aminophylline in the management of acute severe asthma in children

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 22/02/2008	**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
RDC01664

Study information

Scientific Title

Study objectives
To determine whether a bolus of intravenous salbutamol or an aminophylline infusion is the most effective therapy for children with acute severe asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Thames Multicentre Research ethics committee and the local ethics committees.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
1. Bolus of intravenous salbutamol
2. Aminophylline infusion

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Salbutamol, aminophylline

Primary outcome measure
Duration of the need for supplementary oxygen to maintain saturations of above 91%.

Secondary outcome measures
Other end points:
1. Asthma severity score two hours after starting intravenous therapy
2. Time to stopping intravenous therapy
3. Time to decision to discharge subject

Overall study start date
10/01/2000

Completion date
10/01/2002

Eligibility

Key inclusion criteria
1. Age 1 to 15 years
2. Acute severe asthma with an asthma severity score of greater than 7
3. Poor response to 3 "back to back" salbutamol/ipratropium nebulisers with an improvement in asthma severity score of less than 2

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
44

Key exclusion criteria
1. A life threatening exacerbation
2. An underlying respiratory disease other than asthma
3. Cardiac disease
4. Treatment with a medication that alters the metabolism of aminophylline

Date of first enrolment
10/01/2000

Date of final enrolment
10/01/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
West Middlesex Hospital
Isleworth
United Kingdom
TW7 6AF

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (UK)

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	01/04/2003		Yes	No