ISRCTN65396765 https://doi.org/10.1186/ISRCTN65396765

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

| | | |
|---|---|---|
| **Submission date**<br>23/01/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>23/01/2004 | **Overall study status**<br>Completed | |
| **Last Edited**<br>22/02/2008 | **Condition category**<br>Respiratory | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Alex Habel

**Contact details**
West Middlesex Hospital
Isleworth
United Kingdom
TW7 6AF

## Additional identifiers

**Protocol serial number**
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

### Study type(s)
Treatment

### 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(s)
Duration of the need for supplementary oxygen to maintain saturations of above 91%.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
1 years

### Upper age limit
15 years

### Sex
All

### 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
United Kingdom

England

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

# Sponsor information

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

# Funder(s)

### Funder type
Government

### Funder Name
NHS Executive London (UK)

# 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 | 01/04/2003 | | Yes | No |