

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/02/2008	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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