

Randomised controlled trial of nebulised and metered dose inhaler via spacer salbutamol in acute moderate to severe asthma

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/10/2017	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0013133760

Study information

Scientific Title
Randomised controlled trial of nebulised and metered dose inhaler via spacer salbutamol in acute moderate to severe asthma

Study objectives

In acute moderate to severe asthma, is inhaled salbutamol delivery improved by using a metered dose inhaler and spacer device compared with a gas driven jet nebuliser?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Respiratory: Asthma

Interventions

Patients with acute moderate to severe asthma will be randomised to receive inhaled salbutamol either by gas driven nebuliser or by metered dose inhaler and spacer device. Patients will be given oxygen by nasal prongs and an assessment of their asthma severity made. Those with life threatening features will be enrolled. After randomisation they will receive 20 puffs (2 mg) of salbutamol via the spacer device (Volumatic) or 20 puffs of placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

salbutamol

Primary outcome(s)

Main outcome measure peak expiratory flow rate (PEFR) (baseline - 15 minutes post salbutamol) and (baseline - 15 minutes post second dose of salbutamol)

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/03/2004

Eligibility

Key inclusion criteria

Adult patients presenting to the emergency department with acute moderate to severe asthma. They will have auscultatory expiratory wheeze and dyspnoea. The severity of their asthma will be determined by reference to the British Thoracic Society (BTS) guidelines on the management of acute asthma. Patients will be excluded if they have any life threatening features as defined in the BTS guidelines.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/03/2003

Date of final enrolment

01/03/2004

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Acute Medicine

London

United Kingdom

SE1 7EH

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Guy's and St Thomas' NHS Trust (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes