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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 18/10/2017	**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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2003

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

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

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

England

United Kingdom

Study participating centre
Acute Medicine
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St Thomas' NHS Trust (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