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The Bronchodilator Effect of Ultrafine Particles of Salbutamol

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/03/2020	Respiratory	[ ] 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
N0265126517

Study information

Scientific Title
The Bronchodilator Effect of Ultrafine Particles of Salbutamol

Study objectives

Do ultrafine particles of inhaled salbutamol generated from a standard nebulised dose (2.5 mg) cause measurable bronchodilation in patients with asthma?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Double-blind random-order placebo-controlled accumulative dose-response study

Study type(s)
Treatment

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

Interventions
This is a double blind, random-order, placebo-controlled accumulative dose-response study exploring the bronchodilator effects of ultrafine particles of salbutamol in a group of subjects with asthma. The placebo limb will use ultrafine particles of 0.9% saline, generated in an identical way to the active (salbutamol) aerosol.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
05/09/2004

Eligibility

Key inclusion criteria

1. Age >18 years
2. The presence of mild to moderate asthma
3. Willingness and ability to give written informed consent

Potential volunteers will be identified from two sources; prospectively from patients attending Dr D Thickett's respiratory out-patient clinics at UHB trust, and from poster advertisements displayed in the staff common rooms of the Trusts critical care units. In each case, interested parties will be invited to contact the principal investigator by phone to discuss possible participation further. If they would still like to consider participation they will be sent a volunteer information sheet, a copy of the consent form and a 'reply paid' slip by mail. On receipt of the reply slip, the principal investigator will contact them again by phone to arrange a mutually convenient date for them to attend for the first study day. Formal informed written consent will be obtained when participants attend for the first study day. At no time will the participants be pressurised into taking part in any way. No inducements will be offered, but traveling expenses will be refunded if requested.
Participants will be asked if they would like their general practitioners to be informed of their participation in the study. If so, a letter explaining the study and detailing the individual's participation will be sent by first class post to the general practitioner on the first study day.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. The use of > 1000 mcg Beclomethasone (or equivalent) per day
2. Unstable asthma
3. Inability or unwillingness to discontinue long acting and oral bronchodilators for 24 hours, and all short acting bronchodilators for 4 hours prior to each study.

Date of first enrolment
05/09/2003

Date of final enrolment
05/09/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration