# The Bronchodilator Effect of Ultrafine Particles of Salbutamol

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr W S Tunnicliffe

#### Contact details

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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

#### Study design

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

#### Primary study design

Interventional

## 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** 

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