

# The Bronchodilator Effect of Ultrafine Particles of Salbutamol

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/03/2020	<b>Condition category</b> 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

**Contact name**  
Dr W S Tunnicliffe

**Contact details**  
Respiratory Medicine  
Selly Oak Hospital  
Birmingham  
United Kingdom  
B29 6JD  
+44 (0)121 627 1627  
abc@email.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

05/09/2003

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

8 adult volunteers

**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**

England

United Kingdom

**Study participating centre**

Selly Oak Hospital

Birmingham

United Kingdom

B29 6JD

## 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**

University Hospital Birmingham 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