

Determine if counselling patients on how to use Metered Dose Inhalers improves quality of life

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/07/2010	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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
N0626168608

Study information

Scientific Title

Study objectives

Does an inhalation training aid designed for those using a Metered Dose Inhaler (MDI) maintain the correct inhalation technique after a patient has received training/counselling?

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)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Respiratory: Asthma

Interventions

Patients will have their inhalation technique assessed whilst inhaling from a placebo inhaler. Those with a good technique will be placed in the control group. Those with a poor technique will form the intervention group. Subjects in the intervention group will be randomised into a group that receives verbal counselling on how to use their MDI and a group that also receives the verbal counselling with the addition of the Two Tone Training Aid.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Changes in inspiratory flow rates through MDIs.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2005

Completion date

01/03/2006

Eligibility

Key inclusion criteria

1. Asthma
2. Patients using at least one MDI without a spacer device
Prescribed a preventer inhaler
3. Age 3-65 - Group 1: 3-6 years, Group 2: 7-17 years, Group 3: 16 to 65 years
4. Written signed consent

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

120 patients will be recruited aged <17 and 17-65 years (40 participants in each of the three groups).

Key exclusion criteria

1. Patients experiencing an acute exacerbation of asthma or receiving oral prednisolone in the four weeks prior to recruitment
2. Patients with other illnesses adversely affecting the respiratory system or evidence of fixed respiratory obstruction
3. Deaf or unable to distinguish between one and two tones with the Two-Tone trainer
4. Chronic obstructive pulmonary disease (COPD)

Date of first enrolment

01/03/2005

Date of final enrolment

01/03/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

School of Pharmacy

Bradford

United Kingdom

BD7 1DP

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Bradford South and West Primary Care 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2007		Yes	No