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

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2010	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
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
+44 (0)20 7307 2622
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