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A study to test the efficacy of the Mag-Flo inhaler tuition device

Submission date 29/09/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Stopped	
Last Edited 01/05/2008	**Condition category** 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
N0265160802

Study information

Scientific Title

Study objectives
To test whether a group of subjects who have been taught how to use their inhaler and then trained with the Mag-flo device can perform the inhalation better than a group only receiving the usual training instruction.

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)
Not Specified

Participant information sheet

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

Interventions
Fyne-Dynamics will supply conventional Mag-Flo devices for patient use. They will also supply special research devices that tog how long the inhalation lasted with flows between 30 and 60 L /min once triggered and also log the total time of the inhalation following the trigger. The operator marks electronically when the subject starts the breath in sc the time to achieve the trigger flow cart be estimated, The research devices can operate with the green light blanked out (blinded) so the training prompt from the device is not evident to the user when testing how good they are.

The patients involved will be undergoing inhaler tuition as part of their NHS treatment and so no extra patient activity is involved.

Design
Patients will be randomised into one of two Groups. The study will be unblinded. Objective measures will be made with no operator rejection of data.
Group 1 will receive standard tuition on how to use their inhaler and will have their ability to perform the manoeuvre documented at the beginning and the end of this initial training. They wilt also be tested 8 weeks fat or using a blinded Mag-Flo device.

Group 2 will receive tuition on bow to use their inhaler and will use the Mag-Flo device in their training, having been told that obtaining the correct flow using the Mag-Flo device is crucial for drug delivery. They will have their ability checked at the beginning and the end of this training. They will take a Mag-Flo home to use as often as they can to check and help train them in the manoeuvre. They will return in 8 weeks and be assessed again with the blinded device.

Measurements
The Mag-Flo device will be used to record 5 inhalations. The total duration of the inhalation and the duration of inhalation in the optimum low range will be recorded. During this assessment of the subjects ability the green light will not be operative in order to check the technique with the subject blinded. The mean duration of the best (i.e. longest time of inhalation in the correct flow range) two attempts writ be analysed as well as the mean and standard deviation of all 5 attempts.
Spirometry to record PD/I, FVC and REF wilt he performed by technicians blind to he subjects grouping and will be according to British Thoracic Society guidelines before and 20 minutes after inhaling their prescribed dose of inhaler drug. Patients will fill in a satisfaction questionnaire about their perception of the device and how they got on with their inhaler.

Protocol
1. Patients attend having desisted from any bronchodilator inhaler therapy as per routine laboratory practice and will have their spirometry recorded,
2. They are instructed an how to use the powder inhaler and with a blinded Mag-Flo the duration of satisfactory flow v/ill be measured on 5 separate attempts.
3. Group 1 subjects will have further tuition on how to optimise the use of the inhaler and at the end of the test session the duration of satisfactory flow will be measured again with a blinded Mag-Flo on 5 separate attempts, of which the first ones are used to deliver the active drug.
3.Group 2 subjects will have further tuition en hew to optimise the use of the inhaler using an active Mag-Flo as a guide tothe importance of achieving the right tow. At the end of the test session the duration of satisfactory flow will be measured again no 5 separate attempts, of which the first ones are used to deliver the active drug.
4. Record spirometry 20 minutes later.
5. Group 1 subjects leave to se their inhaler as prescribed.
5. Group 2 subjects leave with an active Mag-Flo to have at hems to help them monitor and learn bow to achieve the correct flow when using their inhaler as prescribed.
6. Subjects return in 5 weeks and have their spiromety recorded having desisted from any bronchodilatar inhalers

Intervention Type
Device

Phase
Not Specified

Primary outcome measure
Measurements: the Mag-Flo device will be used to record 5 inhalations. The total duration of the inhalation and the duration of inhalation in the optimum low range will be recorded. During this assessment of the subjects ability the green light will not be operative in order to check the technique with the subject blinded. The mean duration of the best (i.e. longest time of inhalation in the correct flow range) two attempts writ be analysed as well as the mean and standard deviation of all 5 attempts.
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grouping and will be according to British Thoracic Society guidelines before and 20 minutes after inhaling their prescribed dose of inhaler drug. Patients will fill in a satisfaction questionnaire about their perception of the device and how they got on with their inhaler.

Secondary outcome measures
Not provided at time of registration

Overall study start date
14/06/2005

Completion date
14/06/2008

Reason abandoned (if study stopped)
So few patients at this Trust were being selected for powder inhaler devices due to cost.

Eligibility

Key inclusion criteria
All outpatients referred by their clinician for inhaler training by staff at the Lung Investigation Unit at the Queen Elizabeth Hospital will be invited to partake in the study. Patients with a clinical diagnosis either of asthma or chronic obstructive pulmonary disease can be entered.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Initially a total of 30 patients will be recruited. As of May 2008, trial stopped due to poor recruitment.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
14/06/2005

Date of final enrolment
14/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Respiratory Medicine
Birmingham
United Kingdom
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Sponsor information

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

Sponsor details
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Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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