

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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 log 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 so the time to achieve the trigger flow can 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 will also be tested 8 weeks later or using a blinded Mag-Flo device.

Group 2 will receive tuition on how 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 will be analysed as well as the mean and standard deviation of all 5 attempts.

Spirometry to record PD/I, FVC and REF will be performed by technicians blind to the 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 on how to use the powder inhaler and with a blinded Mag-Flo the duration of satisfactory flow will 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 on how to optimise the use of the inhaler using an active Mag-Flo as a guide to the importance of achieving the right flow. At the end of the test session the duration of satisfactory flow will be measured again on 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 use their inhaler as prescribed.
5. Group 2 subjects leave with an active Mag-Flo to have at home to help them monitor and learn how to achieve the correct flow when using their inhaler as prescribed.
6. Subjects return in 5 weeks and have their spirometry recorded having desisted from any bronchodilator inhalers

Intervention Type

Device

Phase

Not Specified

Primary outcome(s)

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Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Respiratory Medicine

Birmingham

United Kingdom

B29 6JD

Sponsor information

Organisation

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

Funder(s)**Funder type**

Government

Funder Name

University Hospital Birmingham NHS Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration