

Measurement of, and psychological intervention with, partial adherence to inhaled antibiotic therapies in adults with cystic fibrosis

Submission date
30/09/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
30/09/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
11/07/2011

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N0436130480

Study information

Scientific Title

Study objectives

1. To determine factors that affect adherence to nebuliser treatment in cystic fibrosis patients
2. To evaluate a psychological intervention designed to improve adherence in those whose adherence is less than 80%

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

Nutritional, Metabolic, Endocrine: Cystic fibrosis

Interventions

Database analysis; Questionnaire; Randomised controlled trial (psychological intervention versus no psychological intervention); Before-after trial.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. The difference in adherence pre and post intervention. This will be measured using the ProDose adaptive aerosol delivery system, which records patient usage data
2. The relationship between adherence and clinical outcome such as forced expiratory volume (FEV1), use of additional antibiotic treatment and patients' own psychopathology (measured using questionnaires)

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/11/2006

Eligibility**Key inclusion criteria**

1. Male and female patients with a diagnosis of cystic fibrosis
2. 18+ years of age
3. Taking nebulised colistin through the ProDose Adaptive Aerosol Delivery (AAD) system for cystic fibrosis
4. Able to use a nebuliser mouthpiece

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/03/2003

Date of final enrolment

01/11/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Academic Unit Psychiatry & Behavioural Sciences

Leeds

United Kingdom

LS2 9LN

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

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	01/04/2009		Yes	No