ISRCTN86935165 https://doi.org/10.1186/ISRCTN86935165

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
Registration date 30/09/2004	**Overall study status** Completed
Last Edited 11/07/2011	**Condition category** Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss J E Quinn

Contact details
Academic Unit Psychiatry & Behavioural Sciences
15 Hyde Terrace
University of Leeds
Leeds
United Kingdom
LS2 9LN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
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)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Academic Unit Psychiatry & Behavioural Sciences
Leeds
United Kingdom
LS2 9LN

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS 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	01/04/2009		Yes	No