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To assess the impact of Target Inhalation Mode (TIM) aerosol delivery on the treatment time with nebulised antibiotic therapy in children with Cystic Fibrosis

Submission date
14/03/2011

Recruitment status
No longer recruiting

Registration date
07/04/2011

Overall study status
Completed

Last Edited
17/01/2012

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09-02-RE

Study information

Scientific Title
A pilot randomised controlled trial to assess the impact of Target Inhalation Mode (TIM) aerosol delivery on the treatment time with nebulised antibiotic therapy in children with Cystic Fibrosis

Acronym
TIM CF

Study objectives
With an Adaptive Aerosol Delivery (AAD) device, use of target inhalation mode (TIM) will reduce the length of treatment times for inhalation when compared with standard tidal breathing mode.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Liverpool paediatric ethics committee and date of approval was 25/05/2009

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cystic Fibrosis

Interventions
Target inhalation mode vs tidal breathing mode for delivering aerosolised antibiotic through an adaptive aerosol delivery device

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Treatment time (seconds)

Secondary outcome measures
1. % Adherence to treatment
2. Pseudomonas growth (number of colony forming units on respiratory culture)
3. Pulmonary function (FEV1 and forced vital capacity (FVC), percent predicted for age, sex and height)
4. Adverse events (e.g. wheeze, or increase in wheeze or change in wheeze pattern)
5. Patient withdrawal
6. Patient reported outcomes using Challenges of Living with Cystic Fibrosis (CLCF) questionnaire

Overall study start date
01/06/2009

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Patients with a valid diagnosis (sweat chloride > 60 or two CF causing gene mutations)
2. Airway infection with Pseudomonas aeruginosa requiring long term nebulised Colistin therapy
3. Established on standard Tidal Breathing Mode of delivery using AAD device for Colistin therapy
4. Ability to comprehend use of the TIM device and follow instruction
5. Aged more than or equal to 5 years and able to perform lung function
6. No recent (> 6 weeks) exacerbation of chest condition as defined by
6.1. A deterioration forced expiratory volume in one second (FEV1) more than or equal to 10% from previously recorded value
6.2. Cough
6.3. Change in sputum production

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
20

Key exclusion criteria

1. Patient with first growth of Pseudomonas aeruginosa requiring short term (3 months) colistin therapy
2. Patients prescribed alternate month TOBI and Colistin nebulised therapy
3. Patients with an acute exacerbation respiratory symptoms

Date of first enrolment
01/06/2009

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Alder Hey Children's Hospital
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust (UK)

Sponsor details
Eaton Rd
Liverpool
England
United Kingdom
L12 2AP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
Alder Hey Children's Foundation Trust Endowment Fund (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	01/09/2011		Yes	No