

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

☒ Results

☐ 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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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Pilot randomised controlled trial

Study type(s)

Treatment

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(s)

Treatment time (seconds)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

United Kingdom

England

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

Sponsor information

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

ROR
<https://ror.org/00p18zw56>

Funder(s)

Funder type
Government

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