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# Assessing the impact and safety of Home IntraVenous Antibiotic Treatment (IVAT) for children with cystic fibrosis

**Submission date**
11/06/2010

**Registration date**
28/06/2011

**Last Edited**
16/12/2019

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
4495

# Study information

### Scientific Title
Assessing the impact and safety of home intravenous antibiotic treatment (IVAT) for children with cystic fibrosis: a non-randomised observational study of risk within a therapeutic process

### Acronym
HIVAT

### Study objectives
1. Examine the consequences of delivering intravenous antibiotic treatment (IVAT) to children with cystic fibrosis (CF) at home
2. The clinical consequences for the child and the psychological consequences for both the carer and the child
3. The long-term aim of the project is to provide a framework to support families with this complex healthcare procedure at home

Hypotheses:
The routine burden of treatment high carer burden during the 14-day period that IVAT is delivered at home will be associated with:
1. Deficits in emotional, psychological and relational well-being for the carer and the child
2. Errors in the delivery of the IVAT
3. Reduced adherence to treatment
4. An augmentation of these effects over time rather than their habituation

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

West Midland MREC approved on the 7th August 2008 (ref: 08/H1208/11)

## Study design
Non-randomised observational validation of investigative/therapeutic process

## Primary study design
Observational

## Secondary study design
Non randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Quality of life

## 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, respiratory disease

## Interventions
1. Quantitative inquiry: A within-group prospective study of risk will compare high burden periods, indexed by the delivery of intravenous antibiotic therapy (IVAT) at home with moderate burden when routine treatments are administered
2. Longitudinal statistical modelling techniques will determine:
2.1. If high burden is related to disordered mood, reduced adherence and adverse events, 2.2. Whether negative outcomes habituate or augment over time
3. Analyses of repeated measures from individual carer/child dyad will be cast in a growth curve framework
4. Inductive inquiry: Within this quantitative framework a sub-sample of carer/child dyads will be selected for micro-level idiographic exploration of their lived experience of delivering and receiving home-based IVAT
5. The research questions will be open-ended:
5.1. What is it like for a mother to administer a course of IVAT to her child at home?
5.2. What is it like for a child to receive IVAT at home from his or her mother?
6. The quantitative and qualitative findings will be integrated for a description of the carer/child experience
7. Home IVAT: Complex healthcare treatment (intravenous antibiotic treatment) delivered by lay caregivers in the community
8. Follow up length: 12 months

## Intervention Type
Other

## Phase
Not Applicable

### Primary outcome measure
Adverse event score: untoward occurences during routine T1 and IVAT time T2

### Secondary outcome measures
1. Adherence: during routine treatment T1 and IVAT treatment T2
2. Disordered mood (depression and anxiety) in caregivers: Routine treatment T1 and IVAT treatment T2

### Overall study start date
11/03/2009

### Completion date
28/05/2010

## Eligibility

### Key inclusion criteria
1. Children aged 13 years or under
2. Confirmed diagnosis of CF for at least one year
3. Caregiver has opted to conduct the IVAT procedure him or herself at home
4. Target gender: male and female

### Participant type(s)
Patient

### Age group
Child

### Upper age limit
13 Years

### Sex
Both

### Target number of participants
UK sample size: 150

### Total final enrolment
45

### Key exclusion criteria
1. Caregivers administering end-of-life care
2. Profound mental, physical or social problems involving statutory services

### Date of first enrolment
11/03/2009

### Date of final enrolment
28/05/2010

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Academic Child Mental Health Unit**
Liverpool
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L12 2AP

# Sponsor information

### Organisation
Royal Liverpool Children's NHS Trust (UK)

### Sponsor details
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
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### Sponsor type
Hospital/treatment centre

### Website
http://www.alderhey.org.uk/

### ROR
https://ror.org/00p18zw56

# Funder(s)

### Funder type
Hospital/treatment centre

**Funder Name**
Alder Hey Children's Hospital (UK)

**Funder Name**
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0706-10381)

# Results and Publications

**Publication and dissemination plan**
2010 results in: https://doi.org/10.1016/S1569-1993(10)60408-0 (added 13/12/2019)

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration