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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

Protocol serial number
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

Study type(s)
Quality of life

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(s)
Adverse event score: untoward occurences during routine T1 and IVAT time T2

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Upper age limit
13 years

Sex
All

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
United Kingdom

England

Study participating centre
Academic Child Mental Health Unit
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
Royal Liverpool Children's NHS Trust (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration