

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

Submission date
11/06/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
28/06/2011

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
16/12/2019

Condition category
Nutritional, Metabolic, Endocrine

☐ 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 occurrences 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

United Kingdom

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

West Derby

Liverpool

England

United Kingdom

L12 2AP

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](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