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Cumulative EFfects of Intravenous Treatments in Cystic Fibrosis

Submission date	Recruitment status	[ ] Prospectively registered
30/10/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/01/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/12/2017	Nutritional, Metabolic, Endocrine	[ ] 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
09025

Study information

Scientific Title
Cumulative EFfects of Intravenous Treatments in Cystic Fibrosis: a cross-sectional observational study

Acronym
CEFIT CF

Study objectives
Cumulative exposure to intravenous treatments causes decreased glomerular filtration rate and impaired hearing in paediatric cystic fibrosis patients.

On 14/02/2012 the overall trial end date was changed from 01/11/2011 to 31/12/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Nottinghamshire Research Ethics Committee, 25/08/2009, ref: 09/H0407/23

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Andrew Payle, the study administrator, at Andrew.Prayle@nottingham.ac.uk to request a patient information sheet

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

Interventions
As an observational study, there is only one arm. After consent, each patient has a Chromium 51 EDTA based glomerular filtration rate (GFR test). A hearing assessment is performed, which consists of a combination of pure tone audiogram, a tympanogram, and distortion product otoacoustic emissions (DPOAE). Blood and urine samples are taken for biomarkers of kidney

injury. A saliva sample is taken for genetic analysis. These interventions will take place in hospital over a 5-hour visit. The cumulative lifetime exposure to aminoglycoside and other intravenous treatments is calculated retrospectively by reviewing the patient notes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The prevalence of chronic kidney disease (GFR less than 80 ml/min/1.73 square metres)
2. The prevalence of hearing impairment
3. The association between cumulative lifetime exposure to intravenous aminoglycosides and GFR will be explored with multiple regression, after adjustment for potential confounders

Both primary and secondary outcomes will be assessed when all patients have completed the study protocol.

Secondary outcome measures
1. Cystatin C in the blood
2. Agreement between cystatin C based formula for GFR and measured GFR (using Cr51EDTA)
3. Genetic analysis methods will depend upon the numbers of participants who have poor kidney function or hearing impairment. Thus after preliminary data regarding these are available, a plan for genetic analyses will be proposed.

Both primary and secondary outcomes will be assessed when all patients have completed the study protocol.

Overall study start date
01/11/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Cystic fibrosis (defined as a positive sweat test, or genetic PLUS clinical features, or positive screening test, or CF in sibling)
2. Participant or participants legally acceptable representative must be able to give informed consent
3. Aged 5 years and over, both males and females

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Intravenous antibiotics in the last 2 weeks
2. Participation in another research project which excludes the patient from this study
3. Poor patient prognosis, and the clinician feels that this or other difficult family circumstances would make taking part in the research inappropriate
4. A postive pregnancy test

Date of first enrolment
01/11/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
The University of Nottingham (UK)

Sponsor details
Research Innovation Services
King's Meadow Campus
Lenton Lane
Nottingham

England
United Kingdom
NG7 2NR

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-1207-15025)

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