

Cumulative Effects of Intravenous Treatments in Cystic Fibrosis

Submission date 30/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/01/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/12/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Sex

All

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 positive pregnancy test

Date of first enrolment

01/11/2009

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Queens Medical Centre

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

The University of Nottingham (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration