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Building a picture of inflammatory arthritis in cystic fibrosis

Submission date
05/09/2017

Recruitment status
No longer recruiting

Registration date
11/09/2017

Overall study status
Completed

Last Edited
22/09/2017

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cystic Fibrosis is a condition that causes the lungs and digestive system clogged with mucus. Cystic Fibrosis associated arthropathy (CFA) is a condition thought to affect up to 10% of the CF population. It causes joint pain and swelling which is often intermittent, but which may become long-lasting. The aim of this study is to review patients with CF and inflammatory musculoskeletal symptoms with the aim of better understanding the phenotype and range of this condition. This will help to identify patients who need further investigation and treatment for joint symptoms. It will also aid future studies considering treatment options for this condition.

Who can participate?
Patients aged 16 or over who have CF, and who report joint swelling, morning stiffness, or impact on activities of daily living due to joint symptoms as well as patients with CF who do not have joint issues.

What does the study involve?
Participants are asked to attend an appointment for a clinical history and examination to be completed, and an ultrasound of their joints. Following this review, participants are asked to reattend only if their joint symptoms flare. They are asked to contact the CF unit should this occur. A follow-up telephone call is used at the end of the study period to confirm flare patterns. Participants with CF without joint disease have one visit combined with a routine clinic visit to include blood tests and ultrasound along with a clinical examination. They will also have a telephone call at the end of the study to ensure that they have not developed joint symptoms in the intervening time period.

What are the possible benefits and risks of participating?
Participants may benefit from better identification for patients seen with inflammatory joint disease so that treatment options may be discussed (in current form, evidence for these is extrapolated from other rheumatic diseases). In some cases, identification that pain is not currently associated with inflammation in the joint, and advice can be given on this basis and other associations with pain looked for. There are risks of bruising and minor discomfort for blood tests. There is a small risk of radiation with the ultrasounds associated with x-rays of

symptomatic joints - these will only be carried out if they would be done so in routine clinical practice.

Where is the study run from?
1. Manchester Adult Cystic Fibrosis Centre (UK)
2. Leeds Adult Cystic Fibrosis Centre (UK)

When is the study starting and how long is it expected to run for?
April 2017 to November 2018

Who is funding the study?
1. CF trust (UK)
2. Manchester Adult CF unit (UK)
3. Leeds University (UK)

Who is the main contact?
Dr Elizabeth Clarke
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Contact information

Type(s)
Public

Contact name
Dr Elizabeth Clarke

ORCID ID
http://orcid.org/0000-0002-6703-6281

Contact details
Manchester Adult Cystic Fibrosis Unit
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Manchester
United Kingdom
M23 9LT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
awaited

Study information

Scientific Title
Identifying a Phenotype in Cystic Fibrosis Associated Arthritis

Acronym
PAC

Study objectives
This study aims to review patients with CF and inflammatory musculoskeletal symptoms with the aim of better understanding the phenotype and range of this condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Observational cohort with control arm

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cystic Fibrosis Associated Arthropathy

Interventions
This is an observational study looking at cystic fibrosis associated arthropathy patterns of disease, to include clinical history and examination, serology, and ultrasound.

Patients with CF who have inflammatory-sounding joint symptoms are recruited to this observational cohort study. Participants attend a baseline visit in which they are seen by the clinical fellow to gain background medical information, a clinical examination, collect blood tests and complete an ultrasound of joints when they are not flaring. Xrays of joints are requested only for patients in whom it would be clinically indicated (unremitting or longstanding pain and swelling). Joint aspiration is carried out only where there is a significant effusion, in which case it would be clinically indicated. Investigation with blood tests includes inflammatory markers; urate (for gout); rheumatoid factor and anti CCP (associated with rheumatoid arthritis) and HLA-B27 (associated with seronegative spondyloarthropathies). Participants are then seen as and

when their joint symptoms flare in order to characterise the patterns of events and to gain clinical examination data, ultrasound imaging and bloods to gain a better picture of the disease. A telephone call at the end of the study is used to confirm patterns of disease flare over the study period.

25 patients with CF who do not have joint disease act as healthy control participants. These patients will have one visit combined with a routine clinic visit to include a medical history and clinical examination, blood tests and ultrasound.

Intervention Type
Other

Primary outcome measure
Patterns of disease identified by clinical manifestation, ultrasound findings and serology over a 9 month follow-up.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/04/2017

Completion date
01/11/2018

Eligibility

Key inclusion criteria
1. Cystic Fibrosis
2. Peripheral joint disease including current or previous joint swelling affecting activities of daily living
3. Aged over 16
4. Attendance at either the Manchester or Leeds CF centre

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
75

Key exclusion criteria
1. Joint problems that when reviewed sound primarily biomechanical or have another non-inflammatory cause
2. Under 16 years

Date of first enrolment
14/10/2017

Date of final enrolment
14/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Adult Cystic Fibrosis Unit
University Hospitals South Manchester
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Leeds Cystic Fibrosis Centre
Gledhow Wing
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University Hospital South Manchester

Sponsor details
Southmoor Road
Wythenshawe
Manchester
England
United Kingdom
M23 9LT
+44 161 998 7070
sian.hanison@manchester.ac.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
Cystic Fibrosis Trust

Alternative Name(s)
Cystic Fibrosis, CF

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Manchester Adult Cystic Fibrosis Unit

Funder Name
Leeds University

Results and Publications

Publication and dissemination plan
Dissemination of results to participants and the CF community via our research newsletter and our unit facebook and twitter pages when possible. Planned publication in a high-impact peer reviewed journal 01/02/2020. A copy of the protocol will be available following review by the ethics committee.

Intention to publish date

01/02/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to the raw data will be held separately from any patient identifiers for 5 years by the trust (UHSM) who are our sponsor. Requests for access would be via the trust but generally the information has been gather for a specific reason (this study) and could not therefore be used for another purpose.

IPD sharing plan summary

Not expected to be made available