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Investigating genes in patients with polymyositis and dermatomyositis

Submission date
10/08/2010

Recruitment status
No longer recruiting

Registration date
21/09/2010

Overall study status
Ongoing

Last Edited
04/02/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM) belong to a group of inflammatory muscle disorders, of unknown cause, that are characterised by skeletal muscle inflammation and progressive muscular weakness, which can be debilitating and chronic in nature (occasionally fatal). The current treatment options for these conditions are steroids and various other immunosuppressive drugs. However, these are usually only partially effective at reducing symptoms, and their toxic side effects also limit their usefulness. In order to develop more specific and therefore more effective treatments for myositis, it is important to understand the exact mechanisms that cause the disease in the first instance. The aim of this study is to identify genes that are associated with the development and clinical characteristics of inflammatory muscle diseases. By understanding the genetic cause of the diseases, it should be possible to design specific drugs for treating the conditions in the future.

Who can participate?
Patients aged 18 or over with PM, DM or IBM.

What does the study involve?
Participants are asked to give 20 ml of blood. These blood samples, along with the patient's clinical details, are then be sent to the Centre for Integrated Genomic Medical Research (CIGMR) at The University of Manchester, where the genetic analysis takes place.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Manchester University and Salford Royal NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2000 to December 2030 (updated 04/02/2021, previously: January 2020)

Who is funding the study?
Manchester University and Salford Royal NHS Foundation Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01171573

Secondary identifying numbers
7996

Study information

Scientific Title
Identification of disease susceptibility genes associated with development and clinical characteristics of primary inflammatory muscle diseases, polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM)

Acronym
UKMYONET

Study objectives
Polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM) belong to a group of inflammatory muscle disorders, of unknown cause, that are characterised by skeletal muscle inflammation and progressive muscular weakness, which can be debilitating and chronic in nature (occasionally fatal). The current treatment options for these conditions are steroids and various other immunosuppressive drugs. However, these are usually only partially effective at reducing symptoms, and their toxic side effects also limit their usefulness.

In order to develop more specific treatments for myositis in the future (and therefore more effective), it is important to understand the exact mechanisms that cause the disease in the first instance. In other similar inflammatory diseases such as rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE), it is known that changes to the Human Leukocyte Antigen (HLA), as well as certain inflammatory cytokines, are involved in both the development and expression of the disease.

As many of the inflammatory mechanisms that cause damage in PM, DM and IBM are similar to those in RA and SLE, it seems likely that similar genetic factors will also be involved in the development and expression of PM, DM and IBM. In order to understand the genetic aspects /causes of myositis, and ultimately develop more effective treatment therapies in the future, patients with PM, DM or IBM, will be asked to give 20 ml of blood. These blood samples, along with the patient's clinical details, will then be sent to the Centre for Integrated Genomic Medical Research (CIGMR), at The University of Manchester, where all of the genetic analyses will take place. By understanding the genetic cause of the disease, it should be possible to design specific drugs for treating the condition in the future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West REC 5 Haydock Park, 04/05/1999, ref: 98/8/86

Study design
Interventional clinical laboratory study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

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
Polymyositis, dermatomyositis and inclusion body myositis

Interventions
Venepuncture, 20 ml of blood collected in EDTA tubes and sent off for genetic and antibody analysis. Genetic analysis is taking place on these samples as an ongoing process and will continue to do so until sufficient numbers have been collected for a conformation Genome Wide Association Scan (GWAS), possibly 2020.

Intervention Type
Genetic

Primary outcome measure
To identify any disease susceptibility genes associated with development and clinical characteristics, measured once conformation GWAS performed (possibly 2020)

Secondary outcome measures
No secondary outcome measures

Overall study start date
06/01/2000

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Skin lesions of (DM):
1.1. Heliotrope rash (violaceous rash and on upper eyelids)
1.2. Gottrons sign (violaceous keratotic macules on extensor aspect of finger joints)
1.3. Violaceous slightly raised rash over elbows/knees
2. Proximal muscle weakness (PM, DM and IBM)
3. Elevated plasma muscle enzymes
4. Myalgia, at rest or with contraction
5. Myopathic changes on electromyogram (EMG)
6. Anti Jo1 Ab

7. Nondestructive arthritis
8. Systemic inflammatory signs (fever, erythrocyte sedimentation rate [ESR] greater than 20, elevated C-reactive protein [CRP], weight loss)
9. Myositic changes on muscle biopsy
10. Additional patients with proven Inclusion Body Myositis (IBM)
11. Male and female, lower age limit of 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 600

Total final enrolment
1947

Key exclusion criteria
1. Below the age of 18 years
2. Myositis secondary to:
2.1. Alcohol or drug abuse
2.2. Non-abusive drug ingestion (e.g with statins, fibrates etc), or
2.3. A recent viral illnesses
3. Unable to give consent due to diminished mental capacity or inability to speak sufficient English
4. Unwilling to give blood samples

Date of first enrolment
06/01/2000

Date of final enrolment
26/08/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Rheumatic Diseases Centre
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Manchester University (UK)

Sponsor details
Centre for Suicide Prevention
Room 2.320, University Place
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United Kingdom
M13 9PL

Sponsor type
University/education

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

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
University/education

Funder Name
Manchester University (UK)

Funder Name
Salford Royal NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2030

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration