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Investigating genes in patients with polymyositis and dermatomyositis

Submission date	Recruitment status	[ ] Prospectively registered
10/08/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2010	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/01/2026	Musculoskeletal Diseases	[X] 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

ClinicalTrials.gov (NCT)
NCT01171573

Protocol serial number
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)
Approved 04/05/1999, NRES committee North West Haydock (HRA NRES centre Manchester 3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ, Manchester, M1 3DZ, United Kingdom; +44 (0)161 6257827; nrescommittee.northwest-haydock@nhs.net), ref: 98/8/086

Primary study design
Interventional

Study design
Interventional clinical laboratory study

Study type(s)
Screening

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

Key secondary outcome(s)
No secondary outcome measures

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. Gottron's 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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 Years

Upper age limit
100 Years

Sex
All

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
United Kingdom

England

Study participating centre
Rheumatic Diseases Centre
Northern Care Alliance NHS Foundation Trust
Salford Royal Hospital
Stott Lane
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Sponsor information

Organisation
Manchester University (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
University/education

Funder Name
University of Manchester

Alternative Name(s)
University of Manchester in United Kingdom, University of Manchester UK, The University of Manchester, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Salford Royal NHS Foundation Trust

Alternative Name(s)
SRFT

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration