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Fibromyalgia symptoms and the immune system

Submission date
20/11/2018

Recruitment status
No longer recruiting

Registration date
15/03/2019

Overall study status
Completed

Last Edited
21/08/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The causes of fibromyalgia syndrome (FMS), a wide-spread chronic (long-lasting) pain condition, are currently unknown. Treatment is often not effective and many patients suffer from unrelenting pain without relief. FMS is linked with additional symptoms, including pain changes at different temperatures, pain in response to pressure in various parts of the body, bowel problems, poor sleep, fatigue and memory problems. Patients can often feel bewildered and distressed by these unexplained symptoms.
Recent research from this research team suggests that many patients have substances called autoantibodies in their blood that cause the FMS symptoms. These autoantibodies also affect the temperature at which patients feel most comfortable. But there is not currently enough evidence on this to enable doctors to inform patients about how common the temperature dependence of FMS is.
This study aims to investigate patients' own perception of the temperature at which they feel at their best, and how a change in temperature affects their other FMS symptoms and their measured sensitivity to pressure. The results from this study, together with the results from previous laboratory tests, will allow doctors to better explain the temperature dependence of symptoms to their patients. Putting patients' experienced symptoms into context with information about the situation of other patients who suffer from the same condition should reduce patients' distress.

Who can participate?
Any English-speaking adult over the age of 18 with a diagnosis of fibromyalgia and symptoms of at least 1 year duration who is not pregnant or breastfeeding.

What does the study involve?
Participants will be asked a series of questions about their health and FMS. There will be a short test of pressure-related pain and skin sensitivity and the opportunity to donate blood to the Liverpool Biobank for our ongoing research into the immune causes of fibromyalgia.

What are the possible benefits and risks of participating?
Doctors currently know very little about FMS and diagnosis is difficult. The knowledge gained from this study will support healthcare professionals to inform patients about these FMS-associated sensitivities and their causes. Better explanation of the underlying causes for these symptoms can reassure patients that their symptoms have a physical cause, reducing distress.

The results might allow doctors to better advise patients in the future about the benefits of different temperatures. The risks of participating very small. Sometimes, following the sensory testing, patients experience residual lingering pain for a few days.

Where is the study run from?
The Walton Centre, Liverpool (UK)

When is the study starting and how long is it expected to run for?
September 2018 to August 2024

Who is funding the study?
UK Medical Research Council (MRC)

Who is the main contact?
Dr Andreas Goebel, Andreas.Goebel@liverpool.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Andreas Goebel

ORCID ID
http://orcid.org/0000-0002-3763-8206

Contact details
Pain Research Institute
University of Liverpool
Liverpool
United Kingdom
L69 3BX
+44 (0)151 529 5526
Andreas.Goebel@liverpool.ac.uk

Type(s)
Scientific

Contact name
Dr Richard Berwick

ORCID ID
http://orcid.org/0000-0002-6895-6127

Contact details
University of Liverpool
Liverpool
United Kingdom

L69 3BX
-
richard.berwick@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40070

Study information

Scientific Title
Autoimmunity-informed Phenotyping In patients with Fibromyalgia syndrome (APIF)

Acronym
APIF

Study objectives
Symptom intensity in fibromyalgia is temperature-dependent. These phenotypic differences are mediated by a biological cause, most likely immunological, by serum IgG autoantibodies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/09/2018, Health Research Authority (HRA) and Health and Care Research Wales (HCRW), ref: 18/WA/0234

Study design
Observational; Design type: Clinical Laboratory Study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Fibromyalgia

Interventions
Eligible patients identified from Walton Centre pain registry will be approached over the telephone and provided with study information by post if agreeable. Those who are happy to participate will attend a 2-hour clinic appointment held by a study doctor/nurse. Consent for the trial will be taken in the appointment. They will then be asked a number of questions pertaining to their health in general and to their fibromyalgia, including current and historical diagnostic criteria. They will undergo brief sensory testing, assessing for pressure pain sensitivity with an algometer and skin touch sensitivity with a brush. If participants agree, they will have a blood sample taken to be stored in the Liverpool BioBank. A series of standard pain questionnaires will then be completed to identify the impact of pain on participant lives and the psychological implications of fibromyalgia. These will include pain intensity on a visual analogue scale (VAS) 0-10, an EQ-5D health questionnaire, a McGill questionnaire of pain characteristics, a Brief Pain Inventory of life interference, a Hospital Anxiety and Depression Scale, a Pain Catastrophising Scale, a Patient Developed Measures questionnaire, work Interferences with a Stanford Presenteeism questionnaire, Experiences in Close Relationships (ECR-R) questionnaire, a Pain Self Efficacy questionnaire, a Revised Fibromyalgia Impact questionnaire, daily stressors and a Pain Detect questionnaire. A member of the study team will call 5-7 days after the visit to confirm temperature pain relationship and to enquire over the presence of lingering pain from the examination from days 1-5.

Intervention Type
Other

Primary outcome measure
1. Patient-reported 'ideal' temperature (i.e. the temperature at which a patients feels most comfortable with least spontaneous pain) by the researchers on interview
2. Change in symptom intensity (including spontaneous pain, pressure induced pain, sleep, fatigue, bowel symptoms, and psychological symptoms such as anxiety and depression) caused by variation in ambient temperature, recorded by the researchers on interview
Unless otherwise defined, the timepoint for all outcome measures is at the clinic visit.

Secondary outcome measures
1. Mechanical pain threshold assessed using a pressure algometer
2. Brush stroke sensitivity (intensity, ticklishness and pain on a VAS 0 to 10 and pleasantness on a VAS (-5 to +5) for both slow and fast brush strokes)
3. Patient-reported pain lingering after mechanical examination from 0 to 5 days recorded during telephone call from researcher 5-7 days after the clinic visit
4. Extent of neuropathic component to pain assessed using the painDETECT questionnaire
5. Health-related quality of life assessed using the EQ-5D questionnaire
6. Pain characteristics assessed using McGill pain questionnaire
7. Interference with life of pain assessed using the Brief Pain Inventory
8. Anxiety and depression assessed using the Hospital Anxiety and Depression Scale (HADS)
9. Pain catastrophising assessed using the Pain Catastrophizing Scale
10. Energy and pain intensity assessed using a a Patient-Developed Measures questionnaire
11. Ability to focus on work assessed using the Stanford Presenteeism Questionnaire

12. Security in relationships assessed using the Experiences in Close Relationships (ECR-R) questionnaire
13. Confidence in ability to conduct life activities while in pain assessed using the Pain Self Efficacy questionnaire
14. Impact of FMS symptoms assessed using the Revised Fibromyalgia Impact questionnaire (FIQR)
15. Ability to deal with emotional burdens and social interactions assessed using a daily stressors questionnaire
16. Patient-reported psychological trauma trigger for FMS by the researchers on interview
17. History of rheumatic disease in participant or first-degree relative by the researchers on interview
Unless otherwise defined, the timepoint for all outcome measures is at the clinic visit.

Overall study start date
01/09/2018

Completion date
31/08/2024

Eligibility

Key inclusion criteria
1. Fibromyalgia syndrome of more than 1 year duration, without other conditions that could explain participant's widespread pain in the view of the investigator
2. ACR Fibromyalgia Criteria 2010 or 1990
3. Aged 18 years and above
4. Average weekly pain intensity of 4/10 or higher on a 11-point numeric rating scale (0-10 NRS)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
113

Key exclusion criteria
1. Pregnant or breastfeeding
2. Unable to read or understand the standard questionnaires

Date of first enrolment
01/11/2018

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Walton Centre
Lower Lane
Liverpool
United Kingdom
L9 7LJ

Sponsor information

Organisation
University of Liverpool

Sponsor details
Research Integrity and Governance Manager
Research Support Office
University of Liverpool / Liverpool Joint Research Office
2nd Floor Block D Waterhouse Building
3 Brownlow Street
Liverpool
England
United Kingdom
L69 3GL
-
sponsor@liverpool.ac.uk

Sponsor type
University/education

Website
https://www.liverpool.ac.uk/

ROR

https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study research team plan to publish in a high-impact journal following trial completion.

Intention to publish date
31/08/2025

Individual participant data (IPD) sharing plan
Access to to the anonymised datasets generated during the current study can be made by request to PI Dr Andreas Goebel (andreas.goebel@liverpool.ac.uk) following trial completion in Autumn 2021. The data will be stored on SPSS/Excel software and held for 30 years. Research data is anonymised and stored separately to participant contact data. Participants will have a unique identification number. Participants have been consented to research data use for fibromyalgia-related research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		01/12/2022	12/02/2024	Yes	No