

# Gene expression profiling in patients with polymyalgia rheumatica before and after symptom-abolishing glucocorticoid treatment

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<b>Registration date</b> 26/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/08/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Polymyalgia rheumatic is a condition that causes swelling, pain and stiffness in parts of the body, such as the shoulders, hips or neck. It affects men and women above the age of 50 and is the most common chronic inflammatory disease in this age group. If left untreated, the disease is very unpleasant and causes by aching, stiff and tender muscles. Treatment with steroids (treatment for swelling) is effective but long-term treatment is required, which may be associated with serious adverse (unwanted) effects. The aim of this study is to extend the understanding of what happened to people with PMR, by profiling the gene expression in muscle tissue from patients who have not taken steroids with PMR and matched non-PMR participants before and after symptom-eliminating treatment with prednisolone (a type of steroid).

### Who can participate?

Patients aged 50 years and older who have aching or stiffness in the neck, shoulders, hips or thighs for one month or more and adults aged 50 and older without PMR and healthy adults aged 50 and years and older.

### What does the study involve?

Participant receive daily 20 mg prednisolone tablets that they take daily for 14 days. Participants are invited for a visit at the research center twice: once before and once after treatment with the treatment. During the two visits, blood samples are taken and a single muscle biopsy is taken from muscle tissue in the neck/shoulder (trapezius) muscles or the thigh muscles.

### What are the possible benefits and risks of participating?

Participants receive 500 Danish kroner for participating. There are no notable risks with participating.

### Where is the study run from?

Bispebjerg Hospital (Denmark)

When is the study starting and how long is it expected to run for?  
January 2005 to June 2017

Who is funding the study?

1. Danish Rheumatism Association (Gigtforeningen) (Denmark)
2. Nordea Foundation (Nordea-fonden) (Denmark)
3. Medical Sciences, Danish Council for Independent Research, (Sundhed og Sygdom, Det Frie Forskningsråd) (Denmark)

Who is the main contact?  
Prof. Henrik Galbo

## Contact information

### Type(s)

Public

### Contact name

Prof Henrik Galbo

### Contact details

Institute for Inflammation Research  
Tagensvej 20  
Copenhagen  
Denmark  
DK-2100

## Additional identifiers

### Protocol serial number

PMR1

## Study information

### Scientific Title

Gene expression in patients with polymyalgia rheumatica and control subjects before and after glucocorticoid treatment

### Study objectives

The aim of this study is to extend the understanding of the pathophysiology of PMR, by profiling the gene expression in muscle tissue from glucocorticoid-naive patients with PMR and matched non-PMR control subjects before and after symptom-eliminating treatment with prednisolone.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethical Committee of Copenhagen Denmark, 15/04/2005, ref: KF[01]261665

### Primary study design

Interventional

### **Study design**

Interventional single-centre exploratory research trial

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Polymyalgia rheumatica

### **Interventions**

Participants are allocated to groups based on their diagnosis. Participants (the patients and the control participants) receive an open-label, once-daily prednisolone tablets 20 mg/day for 14 days.

Participants are invited for a visit at the research center twice, once before and once after treatment with the treatment usually prescribed for the disease. During the two visits, blood samples are taken and a single muscle biopsy will be taken from muscle tissue in the neck /shoulder (trapezius) muscles or the thigh muscles.

The two groups are compared to see the pathophysiology of PMR.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Glucocorticoids (prednisolone)

### **Primary outcome(s)**

Gene expression is measured in symptomatic muscle tissue using the microarray and quantitative real-time PCR methods at baseline and 14 days.

### **Key secondary outcome(s)**

1. Erythrocyte sedimentation rate is measured using standard clinical laboratory procedures at baseline and 14 days
2. C-reactive protein is measured using standard clinical laboratory procedures at baseline and 14 days
3. Clinical symptoms is evaluated by a trained rheumatologist at baseline and 14 days

### **Completion date**

10/06/2017

## **Eligibility**

### **Key inclusion criteria**

Patients:

1. Age 50 years or older
2. Bilateral aching and stiffness persisting for 1 month or more involving two of the following areas: neck or torso, shoulders or proximal regions of the arms, and hips or proximal aspects of the thighs
3. Erythrocyte sedimentation rate >40 mm/h
4. Exclusion of other diagnoses except giant cell arteritis

Control participants:

Aged 50 years or older

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

Patients and control participants:

1. Prior treatment with glucocorticoids
2. Diagnosis of GCA based on obligatory temporal artery biopsy (patients only)
3. Inflammatory conditions other than PMR
4. Cancer during the past 5 years
5. Neuromuscular disease
6. Severe infections
7. Hereditary disposition for type 2 diabetes
8. Thyroid disease
9. Disturbance of calcium homeostasis
10. Uncontrolled hypertension
11. Use of drugs with potential effects on the study parameters

**Date of first enrolment**

01/09/2005

**Date of final enrolment**

01/10/2007

**Locations**

**Countries of recruitment**

Denmark

**Study participating centre**

**Bispebjerg Hospital**  
Institute of Sports Medicine  
Copenhagen  
Denmark  
DK-2400

## Sponsor information

**Organisation**  
Bispebjerg Hospital

**ROR**  
<https://ror.org/00td68a17>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Gigtforeningen

**Alternative Name(s)**  
Danish Rheumatism Association, The Danish Rheumatism Association

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
Associations and societies (private and public)

**Location**  
Denmark

**Funder Name**  
Nordea-fonden

**Alternative Name(s)**  
Nordea Foundation

**Funding Body Type**  
Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

Denmark

## Funder Name

Sundhed og Sygdom, Det Frie Forskningsråd

## Alternative Name(s)

Medical Sciences, Danish Council for Independent Research, Det Frie Forskningsråd, Sundhed og Sygdom, Danish Council for Independent Research, Medical Sciences, DFF, Sundhed og Sygdom, Danish Health Sciences Research Council, Danish Medical Research Council, FSS, DFF

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Denmark

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository ArrayExpress at <http://www.ebi.ac.uk/arrayexpress/experiments/E-MTAB-3671>. The type of data stored is the raw gene expression levels values. This will be made publicly available when the paper is published in the journal. Participants gave general informed consent that covers the publication of the research results in a completely anonymised format.

## IPD sharing plan summary

Stored in repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	07/08/2017		Yes	No