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

Submission date
29/06/2017

Recruitment status
No longer recruiting

Registration date
26/07/2017

Overall study status
Completed

Last Edited
09/08/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 kroners 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Interventional single-centre exploratory research trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Secondary outcome measures
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

Overall study start date
01/01/2005

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

Age group
Senior

Sex
Both

Target number of participants
20

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

Sponsor details
Bispebjerg Bakke 23
Copenhagen
Denmark
DK-2400

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00td68a17

Funder(s)

Funder type
Industry

Funder Name
Gigtforeningen

Alternative Name(s)
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)
Det Frie Forskningsråd, Sundhed og Sygdom, DFF, Sundhed og Sygdom, Medical Sciences, Danish Council for Independent Research, Danish Council for Independent Research, Medical Sciences, 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

Publication and dissemination plan
Manuscript in late-stage peer review.

Intention to publish date
01/08/2017

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 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?
Results article	results	07/08/2017		Yes	No