

Effect of coenzyme Q10 in fibromyalgia patients: study of symptoms and gene expression

Submission date 07/08/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/05/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Fibromyalgia (FM) is a chronic, long-term condition that causes pain all over the body. It affects approximately 2% of the general population. People with the condition may suffer from a generalised increased sensitivity to pain (hyperalgesia) and a wide range of other symptoms such as allodynia (pain caused by stimuli that would not normally be painful), fatigue (extreme tiredness), joint stiffness and migraines. The treatments currently available only work to some extent. It is not known what causes FM but levels of Coenzyme Q10 (CoQ10), a fat-soluble nutrient that we produce naturally in our bodies, have been found to be low in FM sufferers. The purposes of this study are to assess the effect of CoQ10 on the symptoms of FM patients and to look at the conditions inflammatory gene expression profile.

Who can participate?

Patients between 18 and 65 who have been diagnosed with FM

What does the study involve?

Patients are randomly placed into one of two groups. One group will be given CoQ10, and the other group a placebo. We hope to find a novel therapeutic approach for FM

What are the possible benefits and risks of participating?

Preliminary data have shown some improvements in the clinical symptoms for FM sufferers. There are no known adverse effects from the oral CoQ10 treatment.

Where is the study run from?

University of Sevilla, Spain

When is study starting and how long is it expected to run for?

September 2012 to June 2013

Who is funding the study?

Andalusian Federation of Fibromyalgia and Chronic Fatigue Syndrome, Spain

Who is the main contact?
Professor Pedro Bullón
pbullon@us.es

Contact information

Type(s)
Scientific

Contact name
Prof Pedro Bullón

Contact details
University of Sevilla
Department of Periodontology
Dental School
C/Avicena s/n
Sevilla
Spain
41009
pbullon@us.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A pilot randomized placebo-controlled trial of coenzyme Q10 in fibromyalgia patients

Study objectives
Coenzyme Q10 (CoQ10) is an essential electron carrier in the mitochondrial respiratory chain and a strong antioxidant. Low CoQ10 levels has been detected in patients with Fibromyalgia (FM). The purpose of the present work was to assess the effect of CoQ10 on symptoms of patients with FM and evaluate the inflammatory gene expression profile in blood mononuclear cells from FM patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)

University of Sevilla Ethics Committee, 7 July 2012

Study design

Randomised placebo controlled double blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Fibromyalgia

Interventions

The participants will be randomly allocated to the following two arms (randomisation ratio 1:1):

Intervention group:

300 mg ubiquinone capsule (oral) (Pharmanord, Vejle, Denmark) three times daily for 3 months

Control group:

Placebo (lactose powder) in similar capsules twice daily for 3 months

Total duration of follow-up: 90 days

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Coenzyme Q10

Primary outcome measure

1. Coenzyme Q10 levels by High-performance liquid chromatography (HPLC)
2. Oxidative stress by spectrophotometric methods and flow cytometer
3. Inflammation parameters by Enzyme-linked immunosorbent (ELISA) assays
4. Clinical symptoms using diagnostic criteria ACR 1990, Fibromyalgia Impact Questionnaire (FIQ), Visual Analogue Scale (VAS) of pain, Beck Depression Inventory (BDI) (depression), and Pittsburgh test to determinate the quality of dream.

Secondary outcome measures

Gene expression by Real time polymerase chain reaction (PCR)

Overall study start date

15/09/2012

Completion date

01/06/2013

Eligibility

Key inclusion criteria

1. Male and female patients between 18 and 65 years old
2. Has FM according to official diagnostic criteria for FM established in 1990 by the American College of Rheumatology (ACR)
3. Duration of the illness of ten years or less

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

1. History of renal failure (creatinine equal to or superior than 1.8 mL/dL), coronary disease in the last six months, angina, congestive heart disease, diabetes mellitus type one and two
2. Any life-threatening chronic disease (i.e., cancer disease, inflammatory bowel disease and active immune disorders)
3. Rheumatic disease (i.e., inflammatory arthritis, polymyositis, polymyalgia rheumatica)
4. Osteomalacia and osteoporosis
5. Metabolic and endocrine disease (i.e., hypothyroidism and hyperthyroidism, hyperparathyroidism, adrenal insufficiency, metabolic myopathy)
6. Infectious diseases (i.e., Epstein-Barr virus disease, brucellosis)
7. Rheumatic disease of soft tissue and myofascial pain syndrome
8. Parkinsons disease
9. Women to become pregnant or nursing
10. Patients who are enrolled in other clinical trial or patients who participated in other clinical trial in the last 30 days
11. Any psychological or psychiatric disease to compromise the understanding of the

instructions giving by the investigator

12. Any subject to be unable to follow a good complementation of the treatment

13. Any patient who denies to give the informed consent to participate in this trial

Date of first enrolment

15/09/2012

Date of final enrolment

01/06/2013

Locations

Countries of recruitment

Spain

Study participating centre

University of Sevilla

Sevilla

Spain

41009

Sponsor information

Organisation

Andalusian Federation of Fibromyalgia and Chronic Fatigue Syndrome (Spain)

Sponsor details

[Federación Andaluza de Fibromialgia y Fatiga crónica]

C/ Virog local 10 y 11

Jerez de la Frontera - Cádiz

Spain

11406

Sponsor type

Charity

Website

<http://www.confederacionfmfc.org/>

Funder(s)

Funder type

Charity

Funder Name

Andalusian Federation of Fibromyalgia and Chronic Fatigue Syndrome (Spain)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/10/2013		Yes	No