ISRCTN21164124 https://doi.org/10.1186/ISRCTN21164124

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

Submission date
07/08/2012

Recruitment status
No longer recruiting

Registration date
12/09/2012

Overall study status
Completed

Last Edited
28/05/2014

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 spectrophotometic methods and flow cytometer
3. Inflamation 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