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Tianeptine for the treatment of fibromyalgia: a prospective double-blind, randomised, single-centre, placebo-controlled, parallel group study

Submission date
21/09/2006

Recruitment status
No longer recruiting

Registration date
05/10/2006

Overall study status
Completed

Last Edited
05/10/2006

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.institutferran.es/investigacion.htm

Contact information

Type(s)
Scientific

Contact name
Prof Ferran J García-Fructuoso

Contact details
Paseo Manuel Girona, 33
Servicio de Reumatología
Clínica CIMA
Barcelona
Spain
08034
ferran.garcia@cimaclinic.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BP12/2006

Study information

Scientific Title

Study objectives
Fibromyalgia (FM) is a common illness that affects approximately 2.5 to 13% of the general population, of which the majority (10/1) are female. FM is characterised by chronic widespread pain and sleeping problems. Patients with FM frequently have other symptoms such as headaches, nocturnal jaw tightness, morning stiffness, tingling and numbness of arms and legs, irritable bowel, urinary urgency, dryness in the mouth and eyes, cold swollen hands, anxiety and /or depression. Another characteristic of FM is tenderness at palpation in defined points at the neck and lower back areas.

Tianeptine is an antidepressant agent with a novel neurochemical profile. It increases serotonin (5-HydroxyTryptamine [5-HT]) uptake in the brain (in contrast with most antidepressant agents), promotes neuroplasticity and reduces stress-induced atrophy of neuronal dendrites. Like the Selective Serotonin Reuptake Inhibitors (SSRIs) and in contrast with most tricyclic antidepressant agents, tianeptine does not appear to be associated with adverse cognitive, psychomotor, sleep, cardiovascular or bodyweight effects and has a low propensity for abuse. This study assess the efficacy and safety of tianeptine in patients with FM.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité Ético de Investigación Clínica de Clínica, International Centre of Advanced Medicine (Centro Internacional de Medicina Avanzada [CIMA]) (Barcelona, Spain) (reference number: 0036 /2006CIMA), date of approval is 10th August 2006.

Study design
A prospective double-blind, randomised, single-center, placebo-controlled, parallel group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Group one - intervention group: Three month supply of oral Tianeptine (tablets) 12.5 mg every eight hours.
Group two - control group: Identical placebo every eight hours.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Tianeptine (moxonidine)

Primary outcome measure
The primary outcome was improvement in the pain score (10 cm Visual Analog Scale [VAS]) at 24 weeks and Fibromyalgia Impact Qiestionnnaire (FIQ) score.

Secondary outcome measures
1. The tender point score
2. The Hamilton Depression Anxiety inventory (HAD)
3. Short Form (SF-36) health survey.

Overall study start date
01/01/2007

Completion date
01/09/2007

Eligibility

Key inclusion criteria
1. Aged from 40 to 50 years, both genders
2. Diagnosis of fibromyalgia defined by 1990 American College of Rheumatology (ACR) criteria

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Psychiatric illness
2. Major depression
3. Suicidal risk
4. Substance abuse
5. Pulmonary dysfunction
6. Renal impairment
7. Active cardiac disease
8. Liver disease
9. Autoimmune disease
10. Cancer
11. Sleep apnea
12. Chronic fatigue syndrome
13. Inflammatory bowel disease
14. Contraindications to tianeptine

Date of first enrolment
01/01/2007

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Spain

Study participating centre
Paseo Manuel Girona, 33
Barcelona
Spain
08034

Sponsor information

Organisation
Fundacion para la Fibromialgia y el Síndrome de Fatiga Crónica (Spain)

Sponsor details
c/o Joan Güell
184 Local 27
Barcelona
Spain
08028
info@fundacionfatiga.org

Sponsor type
Research organisation

Website
http://www.fundacionfatiga.org

ROR
https://ror.org/03p4nrj93

Funder(s)

Funder type
Research organisation

Funder Name
Foundation for Fibromialgia and Chronic Fatigue Syndrome (Fundacion para la Fibromialgia y el Síndrome de Fatiga Crónica) (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