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

Submission date
16/10/2005

Recruitment status
No longer recruiting

Registration date
07/11/2005

Overall study status
Completed

Last Edited
21/09/2007

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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BP3/2005

Study information

Scientific Title

Study objectives
Fibromyalgia (FM) is a common illness that affects ~ 2.5% of the general population, of which the majority (9/1) are female. FM is characterized by chronic widespread pain and by 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.

Hypothesis:
Sympathetic nervous system function in fibromyalgia seems overactivated. I1-Imidazoline agonist Moxonidine decreases sympathetic nerve activity. This study assess the efficacy and safety of Moxonidine in patients with fibromyalgia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
1. Moxonidine 0.2 mg/12 hours
2. Placebo/12 hours

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
The primary outcome was improvement in the pain score (10-cm visual analog scale [VAS]) at 24 weeks.

Secondary outcome measures
1. Fibromyalgia Impact Questionnaire (FIQ)
2. The tender point score
3. The Hamilton Anxiety and Depression Scale (HADS)

Overall study start date
01/12/2005

Completion date
30/08/2006

Eligibility

Key inclusion criteria
1. Ages eligible for study: 30 - 60 years
2. Genders eligible for study: both
3. 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. 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. Contraindication of Moxonidine

Date of first enrolment
01/12/2005

Date of final enrolment
30/08/2006

Locations

Countries of recruitment
Spain

Study participating centre
Paseo Manuel Girona, 33
Barcelona
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08034

Sponsor information

Organisation
Foundation for Fibromyalgia and Chronic Fatigue Syndrome (Spain)

Sponsor details
Joan Guell
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Spain
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Sponsor type
Charity

Website
http://www.fundacionfatiga.org

ROR
https://ror.org/03p4nrj93

Funder(s)

Funder type
Charity

Funder Name
Foundation for Fibromyalgia 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