

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 07/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/09/2007	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Spain

08034

Sponsor information

Organisation

Foundation for Fibromyalgia and Chronic Fatigue Syndrome (Spain)

Sponsor details

Joan Guell

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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