ISRCTN60217348 https://doi.org/10.1186/ISRCTN60217348

Effects of acupuncture on patients with fibromyalgia

Submission date	Recruitment status	[_] Prospectively registered
03/10/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2016	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CS: PI0436/09; ISCIII-FIS:PI10/00675

Study information

Scientific Title
Effects of acupuncture on patients with fibromyalgia: a multicentre randomised controlled trial

Study objectives
Acupuncture can alleviate the pain experienced by patients with fibromyalgia (FM), either in its simple form or associated with severe depression, to a greater extent than can sham acupuncture. In addition, the application of this technique produces an improvement in patients' well-being, reduces levels of depression, combats dysfunction, enhances health-related quality of life and moderates the consumption of medicaments used as a conventional therapy, by reducing treatment-related disorders, without producing any such disorder itself to any significant degree.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Trials Ethics Committee of the Andalusian Regional Government, 07/04/2010

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

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

Interventions
The participants in the study will receive a total of nine acupuncture sessions (one per week), either true or sham.

A. True acupuncture (TA):
Individualised acupuncture, applied in accordance with pain characteristics and the diagnostic criteria of traditional Chinese medicine, to obtain Deqi (the sensation that ensures the correct localisation of the insertion point and its depth).

B. Sham acupuncture (SA):
The patient lies face down, and the insertion of needles into the dorsal and lumbar regions is simulated.

The treatment sessions, both TA and SA, will be performed at a rate of one per week for nine weeks. The healthcare personnel applying the different treatments have taken a training course of at least 300 hours in the subject and have more than three years practical experience in its application.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Changes in pain intensity, measured on a visual analogue scale (VAS), at the conclusion of treatment (10 weeks)

Key secondary outcome(s)
1. Changes in levels of depression, measured on the Hamilton Scale (HAMD), at the conclusion of treatment and after six months
2. Changes in the overall indicator value and in the various subscales of the Spanish version of the Fibromyalgia Impact Questionnaire (FIQ), at the conclusion of treatment and at six and twelve months following the start of treatment
3. Changes in pain intensity, measured on the VAS, at six and twelve months following the start of treatment
4. Changes in the pain threshold and the number of painful sites identified by an experienced evaluator, using a pressure algometer. Measured by comparing baseline values with those at end of treatment and at six and twelve months.
5. Changes in health-related quality of life, in accordance with version 2 of the SF-12 questionnaire
6. Consumption of antidepressant medication, analgesics and NSAIDs (prescribed or otherwise) at the time the treatment groups are determined and during follow up (at each treatment session, at the end of treatment and after six and twelve months)
7. Treatment expectations and credibility
8. Control of the treatment

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Out-patients
2. Aged over 17 years, either sex
3. Diagnosed with fibromyalgia according to American Rheumatology College (ARC) criteria
4. Have not previously received acupuncture
5. The Hamilton Scale (HAMD) is used to classify the patients into two sub-groups (cut-off point: 21), with or without severe depression

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Suffering pain for a reason other than fibromyalgia
2. Receiving anticoagulant treatment
3. Pregnant or nursing
4. Involved in work-related litigation for reasons concerning fibromyalgia

Date of first enrolment
01/10/2010

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
Spain

Study participating centre
Pain Treatment Unit
Dos Hermanas
Spain
41700

Sponsor information

Organisation
Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain)

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Research organisation

Funder Name
Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain) (ref: PI10/00675)

Funder Name

Andalusian Regional Ministry of Health (Spain) (ref: PI0436/09)

Results and Publications

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	01/08/2016		Yes	No
Protocol article	protocol	28/02/2011		Yes	No