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Does a three week treatment with microcurrents improve the functional level of people with fibromyalgia syndrome?

Submission date 19/03/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 09/09/2010	**Overall study status** Completed	
Last Edited 09/09/2010	**Condition category** Nervous System Diseases	

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
N/A

Study information

Scientific Title
Does a three week treatment with microcurrents improve the functional level of people with fibromyalgia syndrome? A randomised placebo-controlled trial

Study objectives
Fibromyalgia syndrome is a common medical condition characterised by chronic widespread pain and allodynia. Existing data suggest that disturbed central pain processing plays an important role in its pathogenesis.

Microcurrent treatment reduces Fibromyalgia Syndrome (FMS) symptoms and thus improves the functional ability of those affected.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethical Committee of the Hospital Sant Joan (Reus) on the 27th of April 2006 (Ref. No, 06-04-27/ 4proju)

Study design
Single centre single blind randomised placebo controlled study

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 contact details below to request a patient information sheet

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

Interventions
The subjects will be randomised into a microcurrent group and a placebo group. They all will receive two 30 minute sessions a week for three weeks. They will ask to attend all sessions but can leave the study at any time.

Treatment involves applying self-adhesive electrodes to the two areas that the subject find most painful at that moment (Intensity = 100 microamperes; frequency between 30 and 40 Hz; two

channels). The researcher chooses the electrode position on the basis of these indicators and using the research teams predefined protocol, which have standardized the electrode positions. The subject will be then placed in a prone, lateral, or supine position as comfortable as possible with supporting cushions.
The placebo group will believe that the equipment would be switched on and off so that they will think they will receive the same treatment. However, the equipment will remain off at all times and the current will be not applied. This simulation is possible because microcurrents are not sufficiently intense to stimulate the sensitive nerve fibers and thus are not perceived by patients.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Fibromyalgia Impact Questionnaire (Cuestionario de Impacto de la Fibromialgia [CIF])
The values of the CIF are between 0 and 100, 0 being the best state of health and 100 the worst. CIF will be assessed at the start of treatment (CIF0), at the end of the treatment (CIF1) and at one month after treatment (CIF2).

Secondary outcome measures
Visual analog scale (VAS) (0 = no pain, 10 = unbearable pain), assessed at the start of treatment (VAS0), at end of the treatment (VAS1) and at one month after treatment (VAS2).

Overall study start date
01/03/2006

Completion date
01/05/2010

Eligibility

Key inclusion criteria
1. Adult patients of either sex diagnosed with FMS in accordance with the American College of Rheumatologys criteria (final age range at end of recruitment was 33-71 years)
2. Recruited from the Catalan Association for People Affected by FMS

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
44 patients

Key exclusion criteria
1. Suffering from a multiple organic disease
2. Pregnant
3. Patients with a demand-type cardiac pacemaker
4. Receiving physiotherapy treatment or having finished treatment in the previous month

Date of first enrolment
01/03/2006

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
Spain

Study participating centre
Facultat de Medicina i Ciències de la Salut
Reus (Tarragona)
Spain
43201

Sponsor information

Organisation
University Rovira i Virgili (Spain)

Sponsor details
C/Sant Llorenç 21
Reus (Tarragona)
Spain
43201

Sponsor type
University/education

ROR
https://ror.org/00g5sqv46

Funder(s)

Funder type

University/education

Funder Name
University Rovira i Virgili (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