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

	Prospectively registered
19/03/2010 No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Nervous System Diseases	Record updated in last year
	Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Isabel Salvat

Contact details

Facultat de Medicina i Ciències de la Salut C/Sant Llorenç 21 Reus (Tarragona) Spain 43201

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s))

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).

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

https://ror.org/00g5sqv46

Funder(s)

Funder type

University/education

Funder Name

University Rovira i Virgili (Spain)

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?

Participant information sheet 11/11/2025 No Yes