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Role of myofascial trigger points in fibromyalgia

Submission date 10/02/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/03/2011	**Overall study status** Completed	
Last Edited 30/03/2011	**Condition category** Musculoskeletal 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
AFSA Check number 1403

Study information

Scientific Title
Fibromyalgia pain reproduction by manual stimulation of active myofascial trigger points as compared to latent myofascial trigger points in health controls in pain intensity and pain area

Study objectives
It has previously been reported that local and referred pain from active myofascial trigger points (MTPs) in the neck shoulder region contribute to fibromyalgia (FM) pain and that the pain pattern induced from active MTPs can reproduce parts of the spontaneous clinical FM pain pattern. The hypothesis of current study is that the overall spontaneous FM pain pattern can be reproduced by local and referred pain from active MTPs located in different muscles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Region Nordjylland, Denmark, approved on the 8th July 2008 (ref: VN 20080018)

Study design
Randomised single-blind healthy-controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Manual identification of MTPs in different muscles was done by snapping palpation (first to locate a taut band of muscle and place the fingertip at right angles and then move the thumb tip back and forth to roll the underlying fibres) to induce local twitch response and flat palpation (use the padded aspect of the thumb at a right angle to the muscle fibres and apply pressure against the underlying tissue or bone) to induce local pain and referred pain. The applied pressure to each point was about 4 kg and lasted for 10 sec.

EMG registration of spontaneous electrical activity (SEA) is the only electrophysiological method to document the existence of an MTP. In the current study, EMG registration of SEA was used to confirm or refute the existence of an MTP following manual identification. During the EMG needle insertion, a thumb palpated the taut band and located the most tender spot on a taut band and applied slightly downward pressure just enough to fix the underlying tissue in place. The total duration of the study for each subject is 1 hour.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Local pain and referred pain pattern from MTPs, together with the locations of the MTPs are recorded on an anatomic body map. Taken 10 seconds following manual stimulation of an MTP.

Secondary outcome measures
Existence of the spontanous electrical activity with intramuscular electromyography from the MTPs. Taken after manual stimulation of all MTPs in order not to influence the MTP sensitivity by EMG needle insertion.

Overall study start date
01/01/2009

Completion date
30/12/2010

Eligibility

Key inclusion criteria
1. Patients have FM diagnosis confirmed by a physician according to The American College of Rheumatology (ACR) 1990 criteria for the classification of fibromyalgia
2. Control group:
2.1. No current spontaneous pain
2.2. No major pain experience during the past month prior to experiment
2.3. No pain-related diagnoses (e.g., FM, osteoarthritis, rheumatoid arthritis, low back pain, etc.)
3. Participants are female and aged between 20 - 70 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
30 subjects in each group (total = 60)

Key exclusion criteria
1. Pregnancy
2. Drug addiction
3. Infectious diseases
4. Signs of poor cooperation to the study

Date of first enrolment
01/01/2009

Date of final enrolment
30/12/2010

Locations

Countries of recruitment
Denmark

Study participating centre
Fredrik Bajers Vej 7D-3
Aalborg
Denmark
DK-9220

Sponsor information

Organisation
The American Fibromyalgia Syndrome Association, Inc. (AFSA) (USA)

Sponsor details
PO Box 32698
Tucson
United States of America
AZ 85751

Sponsor type
Charity

Website
http://www.afsafund.org/

ROR
https://ror.org/00tmwkm13

Funder(s)

Funder type
Charity

Funder Name
The American Fibromyalgia Syndrome Association, Inc. (AFSA) (USA) (ref: Check Number 1403)

Alternative Name(s)
The American Fibromyalgia Syndrome Association, Inc., AMERICAN FIBROMYALGIA SYNDROME ASSOCIATION, INC., AFSA

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/03/2011		Yes	No