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Increased brain activation after painful stimulation of the forearm muscles in patients with fibromyalgia syndrome

Submission date
02/09/2015

Recruitment status
No longer recruiting

Registration date
24/09/2015

Overall study status
Completed

Last Edited
22/10/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Fibromyalgia syndrome (FMS) is a common long-term condition, which causes widespread muscle and joint pain all over the body. The exact cause of FMS is unknown, but it is thought that a variety of physical, mental and emotional factors are responsible. One theory is that FMS is to do with an abnormal increase of chemicals in the brain (neurotransmitters), which causes people to feel pain more intensely and are more sensitive to pain. Many studies link fibromyalgia with depression, which is also related to abnormal levels of neurotransmitters in the brain, however little is known about how these two conditions might influence each other. The aim of this study is to find out whether the cortex of the brain (which is responsible for consciousness) is more active in people with FMS than in people with depression with no pain and healthy controls.

Who can participate?
Adults with fibromyalgia syndrome, depression with no pain, and healthy age matched controls.

What does the study involve?
Participants receive two different forms of stimulation. In the first stimulation, painful pressure is applied to the forearm of the patient, and in the second, a word-based memory test (verbal fluency test) is performed. Whilst these stimulations are happening, participants undergo a special type of brain imaging which shows which areas of the brain are active, by looking at the amount of blood flow (functional near-infrared spectroscopy). All participants are also asked to complete questionnaires to measure their levels of pain and emotion.

What are the possible benefits and risks of participating?
Participants receive no direct benefits from the study as it is an observational study. There are no risks of participating in the study.

Where is the study run from?
University of Würzburg and University of Tübingen (Germany)

When is the study starting and how long is it expected to run for?
January 2007 to December 2012

Who is funding the study?
University of Würzburg (Germany)

Who is the main contact?
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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
Increased cortical activation upon painful stimulation in fibromyalgia syndrome

Study objectives
Cortical activation upon painful stimulation is increased in patients with fibryomyalgia syndrome compared to patients with depression and no pain and to healthy controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Würzburg Medical School Ethics Committee, 27/01/2009, ref: 12/09

Study design
Non-interventional single-center study observational study.

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

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

Interventions
Twenty five patients with fibromyalgia syndrome, ten patients with unipolar major depression (MD) without pain, and thirty five healthy controls are recruited for the study. Patients undergo functional near-infrared spectroscopy (fNIRS) whilst being subjected to two stimulations:

1. Painful pressure stimulation at the dorsal forearm
2. Verbal fluency test (VFT) to asses cognitive function using memory recall

All patients underwent neurological examination and all subjects were investigated with questionnaires (pain, depression, FMS, empathy).

Intervention Type

Primary outcome measure
Muscular pressure pain: fNIRS measurements were performed during the application of painful pressure on the muscle bulk of the finger extensors of the right side using a calibrated algesiometer. The stimulation conditions were as follows: pressure application for two seconds; pause for ten seconds between two stimuli; total of 40 stimuli, i.e. measurement at baseline and up to 8 minutes after first stimulation.

Secondary outcome measures
Verbal fluency test (VFT): The VFT paradigm consisted of three conditions. Subjects were asked to produce as many different nouns as possible a) starting with a certain letter (A, F, and S), or b) belonging to the same category (animals, fruits, and flowers) or c) to name the days of the week as a control condition. Each condition lasted for 30 sec followed by 30 sec rest. Subjects worked

on nine blocks in total (3 x letters, 3 x categories, 3 x week days), i.e. measurement at baseline and up to 9 minutes after start.

Overall study start date
01/01/2007

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Patients with:
2.1. Fibromyalgia syndrome
2.2. Unipolar major depression (MD) without pain
2.3.Healthy controls

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Other possible differential diagnoses (e.g. rheumatoid arthritis; post-surgery pain)
2. Current or prior cerebral disease (e.g. stroke, cerebral hemorrhage, head trauma)
3. Any clinically relevant psychiatric disorder (examined by systematic psychiatric interview)

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Germany

Study participating centre
University of Würzburg
Department of Neurology
Sanderring 2
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Study participating centre
University of Würzburg
Department of Psychiatry
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Study participating centre
University of Tübingen
Department of Psychiatry
Geschwister-Scholl-Platz
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/03pvr2g57

Funder(s)

Funder type
University/education

Funder Name
University of Würzburg (EFIC-Grünenthal Grant and intramural funds)

Results and Publications

Publication and dissemination plan
We have submitted our manuscript and are awaiting publication in BMC Musculoskeletal Disorders.
After publication of the paper we are planning to disseminate our data on scientific congresses (e.g. German Pain Society).

Intention to publish date
30/09/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/10/2015		Yes	No