ISRCTN01680675 https://doi.org/10.1186/ISRCTN01680675

Pilot study to investigate the endocrinological, physiological and pain-reducing effects of gamma-hydroxybutyric acid in combination with operant behaviour pain therapy on patients with FibroMyalgia Syndrome

Submission date
16/10/2007

Recruitment status
No longer recruiting

Registration date
06/02/2008

Overall study status
Completed

Last Edited
19/05/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Dr. Claudia Spies

Contact details
Charite - Universitatsmedizin Berlin
Chariteplatz 1
Berlin
Germany
D-10117
+49 (0)30 450 531 012/52
claudia.spies@charite.de

Additional identifiers

EudraCT/CTIS number
2005-002475-32

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
050526 FMS

Study information

Scientific Title
Pilot study to investigate the endocrinological, physiological and pain-reducing effects of gamma-hydroxybutyric acid in combination with operant behaviour pain therapy on patients with FibroMyalgia Syndrome

Acronym
FMS

Study objectives
Title in German: Pilotstudie zu den endokrinologischen, peripherphysiologischen und schmerzreduzierenden Effekten von Gamm-Hydroxybuttersäure in Kombination mit operant-verhaltenstherapeutischer Schmerztherapie bei Patienten mit Fibromyalgiesyndrom

In our study we will test the following hypotheses:
1. After the multimodal therapy composed of gamma-hydroxybutyric acid (GHB) and behavioural therapy (operant pain therapy) in the experimental group in comparision with the control group, we expect a decrease of pain-induced damage, the rate of consultations in the last 12 months and the multidimensional pain inventory (MPI) (primary target goals)
2. The intake of GHB in the experimental group increases growth hormone and cortisol and decreases adrenocorticotropic hormone (ACTH). We expect an increase of muscular tension, a decrease of blood pressure, heart rate and resistance of the skin. A potential effect of GHB increases life control and reduces depressive mood (secondary target goals)

On 03/07/2008 the sources of funding field was updated. The previous text was: 'German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) - grant application pending'

On 14/01/2009 the anticipated end date was changed from 01/12/2008 to 01/12/2009.

On 04/02/2010 the anticipated end date was changed from 01/12/2009 to 31/12/2010.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board committee Berlin, Landesamt fur Gesundheit und Soziales (LaGeSo), 30/11/2005, ref: EA1/160/05

Study design
Placebo-controlled double-blind randomised pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
GHB oral

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Gamma-hydroxybutyric acid (GHB)

Primary outcome measure
1. Number of physician consultations in the last 12 months
2. Multidimensional Pain Inventory (MPI)

Outcomes measured at:
1. Pre-examination: start of the intake of study drug
2. Two months after starting the intake of study drug
3. Post-examination: end of the intake of study drug
4. Catamnesis 1: 2 months after the intake of study drug
5. Catamnesis 2: 6 months after the intake of PP

Secondary outcome measures
1. Muscular tension
2. Blood pressure
3. Heart rate
4. Resistance of the skin
5. Assessment of life control and depressive mood

Outcomes measured at:
1. Pre-examination: start of the intake of study drug
2. Two months after starting the intake of study drug
3. Post-examination: end of the intake of study drug
4. Catamnesis 1: 2 months after the intake of study drug
5. Catamnesis 2: 6 months after the intake of PP

Overall study start date
01/10/2006

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Verified fibromyalgia
2. Female sex
3. Sound command of German language
4. Motivation for therapy
5. Minimum age 18 years
6. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
40

Key exclusion criteria
1. Patients under 18 years or older than 80 years
2. Pregnancy
3. Psychiatric desease
4. Treatment with opioids
5. Treatment with sedative drugs
6. Current intake of anti-depressants
7. Pension demand
8. Patients without the possibility to give their consent
9. Arterial hypertension
10. Epilepsy
11. Severe renal failure
12. Intoxication with alcohol
13. Inclusion in another study within the last 30 days

Date of first enrolment
01/10/2006

Date of final enrolment

31/12/2010

Locations

Countries of recruitment
Germany

Study participating centre
Charite - Universitatsmedizin Berlin
Berlin
Germany
D-10117

Sponsor information

Organisation
Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

Sponsor details
c/o Professor Claudia Spies
Kliniken für Anästhesiologie und operative Intensivmedizin CVK und CCM
Schmerzambulanz Campus Charite Mitte
Charitè Universitätsmedizin Berlin
Chariteplatz 1
Berlin
Germany
D-10117
-
claudia.spies@charite.de

Sponsor type
Other

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Government

Funder Name
Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		09/09/2020	19/05/2022	No	No