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Investigation of the effectiveness of BioFeedBack therapy on Complex Regional Pain Syndrome (CRPS) of the upper extremity

Submission date	Recruitment status	[ ] Prospectively registered
25/10/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/03/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/09/2011	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anja Heymann

Contact details
Charite - Universitatsmedizin Berlin
Department of Anaesthesiology and Intensive Care
Augustenburger Platz 1
Berlin
Germany
13353
+49 (0)304 5055 1012
anja.heymann@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
CRPS-BFB

Study objectives
Biofeedback therapy additional to the standard therapy (blockades of the stellate ganglion) enhances the pain reduction and the functionality of the complex regional pain syndrome (CRPS) -affected extremity compared to standard therapy alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethikkommission der Charite-Universitatsmedizin Berlin on the 20th March 2006 (ref: EA 2/022/06).

Study design
Prospective randomised controlled single centre interventional 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
Complex regional pain syndrome

Interventions
In the active group, the patients get 10 sympathetic blockades of the stellate ganglion. The injections are performed twice a week during five weeks in a standardised manner: all patients get a blockade of the stellate ganglion of the affected side with 10 cc carbostesin 0.25%. The injections are performed twice a week. In addition, these patients are treated by 10 standardised biofeedback sessions (50 minutes) twice a week over five weeks. Biofeedback treatment and blockades are always performed at the same day.

In the control group, the patients get blockades of the stellate ganglion of the affected side in the same manner as in the active group. There is no additional therapy provided.

In both groups, pain, pain coping strategies and sensibility of nerve fibres are measured before starting the treatment and one week after the last treatment. A follow-up is provided six months after the last treatment.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Carbostesin

Primary outcome measure
Analgesia using the Visual Analogue Scale (VAS: 0 = no pain, 10 = unbearable pain).

The primary and secondary outcomes will be measured seven days after the end of the therapy and once again after six months.

Secondary outcome measures
1. Active pain coping strategies using the Questionnaire for Assessment of Level of Coping with Pain (Fragebogen zur Erfassung der Schmerzverarbeitung [FESV])
2. Sensibility of non- or little-myelinated nerve fibres using quantitative sensory testing (QST)
3. Functionality of the affected extremity using the wrist function scale, goniometric and dynamometric measures

The primary and secondary outcomes will be measured seven days after the end of the therapy and once again after six months.

Overall study start date
01/09/2007

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. CRPS I or II of an upper extremity
2. Aged greater than 18 years
3. Stable pain medication during the last two weeks
4. Stable psychoactive medication during the last two months

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Current psychotherapy or psychiatric therapy
2. Major depression
3. Severe cognitive dysfunction or mental disorder
4. Suicidal tendencies
5. Psychosis
6. Participation in other studies in the same time
7. Use of benzodiazepines
8. Drug abuse
9. Contraindications against blockade of the stellate ganglion

Date of first enrolment
01/09/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Germany

Study participating centre
Charite - Universitatsmedizin Berlin
Berlin
Germany
13353

Sponsor information

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

Sponsor details

c/o Prof. Claudia Spies
Department of Anaesthesiology and Intensive Care Medicine
Augustenburger Platz 1
Berlin
Germany
D-13353
+49 (0)304 5055 1002
claudia.spies@charite.de

Sponsor type
University/education

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

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

IPD sharing plan summary
Not provided at time of registration