

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

<b>Submission date</b> 25/10/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/09/2011	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## 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-Universitätsmedizin Berlin on the 20th March 2006 (ref: EA 2/022/06).

### **Study design**

Prospective randomised controlled single centre interventional study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **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(s)**

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.

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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 - Universitätsmedizin Berlin

Berlin

Germany

13353

## Sponsor information

**Organisation**

Charite - University Medicine Berlin (Charite - Universitätsmedizin Berlin) (Germany)

**ROR**

<https://ror.org/001w7jn25>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Charite - University Medicine Berlin (Charite - Universitätsmedizin Berlin) (Germany)

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration