# 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

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# Additional identifiers

**Protocol serial number** 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

## 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

Αll

## 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)

#### **ROR**

https://ror.org/001w7jn25

# Funder(s)

## Funder type

University/education

#### **Funder Name**

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

# **Results and Publications**

# Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration