PEPT versus CBO-therapie bij patiënten met CRPS-I/PD.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23780

Source
Nationaal Trial Register

Brief title
PEPTOC

Health condition

CRPS I
Complex Regional Pain Syndrome Type I
Sympathetic Reflex Dystrophy
Pain Exposure Physical Therapy
Pharmacological treatment
Functional recovery
Posttraumatische Dystrofie

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre, The Netherlands
Dpt. of Surgery
Source(s) of monetary or material Support: Radboud University Nijmegen Medical Centre, The Netherlands
ZonMw, The Netherlands

Intervention

Outcome measures

Primary outcome

Primary outcome measure is the Impairment level SumScore (ISS), which consists of three measurement parameters (pain, active range of motion and temperature) and four measurement instruments (VAS, McGill Pain Questionnaire, goniometry of mobility of joints and skin thermometer).

Secondary outcome

A cost-effectiveness analysis from a societal perspective comparing PEPT to usual care in patients with CRPS will be performed. This will be done along-side the clinical trial.

Study description

Background summary

The current Dutch CBO guideline treatment of Complex Regional Pain Syndrome Type I (CRPS-1) is very disappointing with chronification, disability and subsequent high medical costs and personal suffering. A possible better treatment is intensive function-oriented physical therapy or Pain Exposure in Physical Therapy (PEPT). However, there are no adequate studies performed that demonstrate the efficacy of PEPT and therefore PEPT is lacking in the Dutch CBO CRPS-1 guidelines. Despite a lacking scientific argumentation, the PEPT approach or Macedonian therapy, is now being adopted on a large scale among physical therapists in The Netherlands. There are two level C retrospective cohort studies demonstrating a promising and clinical relevant beneficial effect on pain and function after PEPT. In response to the growing demand for scientific argumentation among doctors and physical therapists with respect to the efficacy of PEPT, we conducted a pilot study at the UMC St Radboud Nijmegen. The results of this pilot study were very promising and therefore, we decided to design a large RCT to investigate the treatment effects and costs in CRPS patients treated with PEPT compared to CRPS patients treated with usual therapy according to the Dutch CBO guidelines.

Study objective

PEPT is expected to be 30% more effective and around three-folds cheaper than usual therapy (CBO).

Study design

After base-line measurements (T0), measurements are performed at three (T1) and six months (T2) after inclusion. Follow-up is at nine months (T3).

Intervention

Treatment group: In the treatment group medication prescribed for CRPS is tapered to zero. No invasive treatments like sympathetic blocks, and/or operations will be performed. After information about the mechanism of action of PEPT in relation to CRPS, patients receive five sessions of PEPT including homework exercises. The basic of PEPT is a function-oriented exercise therapy. The PEPT physical therapist manipulates restricted joints and intensively trains functional skills irrespective of pain experience during or after the therapy. Patients are stimulated to use an active coping style to achieve a clear functional goal in 5 sessions.

Control group: Usual treatment of CRPS according to the Dutch CBO CRPS guideline 2006 including, analgesics (WHO pain ladder), neuropathic drugs, N-acetylcysteine, calcium channel blocker, ketanserine and DMSO (dimethylsulphoxide). On indication, percutaneous sympathetic blocks or spinal cord stimulation will be performed. In addition, patients receive physical therapy with exercises within pain limits (pain contingent), splints and if necessary, aids for ADL activities.

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Eligibility criteria

Inclusion criteria

Patients between 18 and 80 years of age with Complex Regional pain Syndrome (CRPS-1) of either upper or lower extremity according to Bruehl's/IASP criteria between 3 and 24 months after initial injury will be selected for the study.

Exclusion criteria

Patients who do not comply with the inclusion criteria, especially those who have other causes that may explain a pain syndrome will be excluded (IASP criterium).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	75
Type:	Actual

Ethics review

Positive opinion

Date:	30-10-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1973
NTR-old	NTR2090
Other	ClinicalTrials.gov Identifier / ZonMw projectnr. : NCT00817128 / 1709901004
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A