Vasodilators in cold type Complex Regional Pain Syndrome.

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Nitric oxide depending and independing vasodilation in patients with disused, cold type CRPS, will regenerate blood tissue distribution and consequently improve mobility and quality of life factors.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27167

Bron
NTR

Verkorte titel
VasCoTyC study

Aandoening

Cold type complex regional pain syndrome

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Ministry of Economic Affairs The Netherlands, The Reflex Sympathetic Dystrophy Syndrome Association (RSDSA, USA) and Eli Lilly.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tissue blood distribution (thermography and Doppler flow).

Toelichting onderzoek

Achtergrond van het onderzoek

In most cases, adequate pharmacotherapeutic treatment of patients with complex regional pain syndrome type 1 (CRPS1, formerly indicated as post-traumatic dystrophy) in an extremity, who left the acute phase of the disease, is not available. Some pain relief could be obtained, but recovery of the neuro-inflammatory signs of the disease is barely achieved. Chronic CRPS1 could even lead to amputation of the dystrophic hand. Usually this is a direct effect of unbearable continuous pain and disuse of the extremity. Evidence has been found that both disuse and damages of nerve endings could lead to obstructions in the blood distribution of the involved extremity. Improvement of the blood distribution through nitric oxide - cyclic guanosine monophosphate (NO-cGMP) induced vasodilation could attribute to the recovery of this invalidating disease. Therefore, patients will be treated either with isosorbide dinitrate (ISDN), Tadalafil or placebo. In combination with an intensive physiotherapeutic program, this approach could diminish the progression of the disease, stabilize or even cause complete recovery in the patient. In this project, monitoring the patient during the treatment will be achieved by means of objective parameters such as Doppler flow and computer assisted videothermography, whereas clinically important parameters such as pain intensity, mobility and quality of life are registered. Furthermore, blood samples and blister fluid from both the involved and uninvolved extremity will be subjected to measurements of biochemical mediators. These data will provide detailed information of vascular changes in relation to the experience of pain and immobility. Treatment by ISDN or Tadalafil could improve chronic phase CRPS1 and furthermore provide more insight in mechanisms underlying this disabling disease.

Doel van het onderzoek

Nitric oxide depending and independing vasodilation in patients with disused, cold type CRPS, will regenerate blood tissue distribution and consequently improve mobility and quality of life factors.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Subjects are assigned to receive either 1 gram ISDN ointment 1% or placebo 4 times daily (groups 1 and 2) or 1 tablet of 10 mg tadalafil or palcebo daily (groups 3 and 4). The treatment period will be 10 weeks.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Men and women between 18 and 65 years;

2. Established diagnosis of CRPS-1 according to the Bruehl / Budapest criteria.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Coronary atherosclerosis or cerebral sclerosis;

2. Recent heart infarction;

3. Increased intracranial pressure;

4. Severe hypotension;

5. Myocardium insufficiency;

6. Damage of the central nervous system;

7. Contraindication of nitrates;

8. Inflammation of joints;

9. Use of corticosteroids or immunosuppressives;

10. Unable to fill in questionnaires.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2006
Aantal proefpersonen:	76
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-01-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL527
NTR-old	NTR571
Ander register	: N/A
ISRCTN	ISRCTN60226869

Resultaten

Samenvatting resultaten
N/A