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# Vasodilators in cold type Complex Regional Pain Syndrome

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 14/02/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 14/02/2006 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 08/09/2011 | Musculoskeletal Diseases | |

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
NTR571

## Study information

**Scientific Title**

### Acronym
VasCoTyC study

### Study objectives
Nitric oxide dependent and independent vasodilation in patients with disused, cold type CRPS, will regenerate blood tissue distribution and consequently improve mobility and quality of life factors.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Study type(s)
Not Specified

### Health condition(s) or problem(s) studied
Cold type complex regional pain syndrome (CRPS)

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

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
isosorbide dinitrate (ISDN), tadalafil

### Primary outcome(s)
Tissue blood distribution (thermography and Doppler flow).

### Key secondary outcome(s))
Pain, mobility and quality of life.

### Completion date
31/12/2007

## Eligibility

### Key inclusion criteria
1. Men and women between 18 and 65 years
2. Established diagnosis of CRPS-1 according to the Bruehl/Budapest criteria

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
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

### Date of first enrolment
01/02/2006

### Date of final enrolment
31/12/2007

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Erasmus Medical Center**
Rotterdam
Netherlands
3000 CA

# Sponsor information

### Organisation
Erasmus Medical Center (The Netherlands)

### ROR
https://ror.org/018906e22

# Funder(s)

### Funder type
Government

### Funder Name
The Reflex Sympathetic Dystrophy Syndrome Association (RSDSA, USA), Eli Lilly, Ministry of Economic Affairs

# Results and Publications

### Individual participant data (IPD) sharing plan

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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 20/10/2008 | | Yes | No |