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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

Primary study design
Interventional

Study design
Randomised controlled trial

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