

Vasodilators in cold type Complex Regional Pain Syndrome

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/09/2011	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Tissue blood distribution (thermography and Doppler flow).

Secondary outcome measures

Pain, mobility and quality of life.

Overall study start date

01/02/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

76

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)

Sponsor details

Dr Molewaterplein 40/50

Rotterdam

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Sponsor type

Not defined

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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