The effect of Pyridostigmine on patients with CRPS-1.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20521

Source
Nationaal Trial Register

Brief title
Pyridostigmine

Health condition

complex regional pain syndrome, neuropathic pain, neurogenic inflammation,

Sponsors and support

Primary sponsor: TREND
Source(s) of monetary or material Support: BSIK

Intervention

Outcome measures

Primary outcome

1. Pain (VAS score);

2. Motor funcion (AROM);

3. Swelling;

4. Temperature.

Secondary outcome

1. Autonomic functioning;

2. Blood analysis on oxidative stress;

3. Acetylcholine status.

Study description

Background summary

Pyridostigmine: using a Cholinesterase Inhibitor to activate the Cholinergic Anti-Inflammatory Pathway in patients with CRPS-I.

Background of the study:

Complex regional pain syndrome type I (CRPS-I) is a painful and disabling condition which can develop after trauma, such as wrist fracture, distortion or operation, but without preceding incident. CRPS-I is characterized by pain and sensory abnormalities, oedema and sudomotor dysfunction, colour change, limited range of motion and autonomic disturbances (for example excessive sweating of the affected limb). Another symptom is that pain will get worse when the extremity is used more.

Several pathological mechanisms have been suggested to play a role in the development of CRPS-1. This study is based on the assumption that CRPS-1 is caused by neurogenic inflammation, in which free radicals are involved. Although this can not explain all the symptoms we find in this pain syndrome.

Neurogenic inflammation starts as a natural process when peripheral trauma occurs. The following immune reaction starts a cascade of cytokines and a local inflammatory response. The human immune system must also be capable to down-regulate this reaction when a trauma has healed to minimize the local damage obtained by this inflammation. For this regulation two pathway are believed to play a part, the “classical” humoral immunologic pathway and the cholinergic pathway.

The cholinergic pathway is an interesting pathway for therapeutic use, because it is regulated by nerves and thereby a fast way of 'communication'. A key factor of the cholinergic pathway is the neurotransmitter Acetylcholine (ACh) which is excreted by stimulation of the nervus vagus and communicates with the local immune cells (eg. macrophages) by Acetylcholine receptors (AChR), which are expressed on those immune cells. The activated Acetylcholine receptors inhibit the production of cytokines and thereby modulate the inflammation. As a therapeutical options the ACh has to be raised around the immune cells. A possibility to reach a higher level of ACh is to inhibit the Acetylcholinesterase and thereby lower the re-uptake of ACh. In this study a higher level of ACh will be accomplished by the use of Pyridostigmine (cholinesterase inhibitor).

Objective of the study:

Primarily outcome:

The effect of Pyridostigmine (cholinesterase inhibitor) on inflammatory signs as pain, temperature, swelling and functional status of the extremity measured according to TREND protocol (app 1).

Secondary outcome:

Are the patients treated with Pyridostigmine clinically getting better and have less pain?
Side-effects of Pyridostigmine measured by PBSES (appendix 2)

Study design:

This study will be a single-subject-study in which we will follow 10 patients with CRPS-I and evident signs of inflammation (Veldman-criteria). It will be a study with a baseline measurement (A), a titration fase of 3 to 6 weeks and an actual therapeutical fase (B). After 12 weeks of treatment Pyridostimine will be stopped and a new base line will be measured at 14 weeks (A) (A-titration fase-B-A). Further follow-up will take place after 6 months and 12 months (app 3).

Study objective

Pyridostigmine will activate the parasympathetic cholinergic anti-inflammatory pathway and therefore reduce inflammatory signs and symptoms in patients with complex regional pain syndrome.

Study design

1. 3 weeks titration phase, with continuous evaluations;

2. Then, week 4, 6, 8, 10, 14.

Intervention

Pyridostigmine in an individual dosage.

Contacts

Public
VUmc, afdeling 6F kamer 002, anesthesiologie
Postbus 7057
S.G.L. Fischer
Amsterdam 1007 MB
The Netherlands
+31 (0)20-4440293
Scientific
VUmc, afdeling 6F kamer 002, anesthesiologie
Postbus 7057
S.G.L. Fischer
Amsterdam 1007 MB
The Netherlands
+31 (0)20-4440293

Eligibility criteria

Inclusion criteria

Patients with CRPS-1 according to Veldman criteria, autonomic alterations like hypo/hyper hydrosis, altered hair/nail growth, unsatisfactory results of standard treatment, ability to give informed consent, age >18.

Exclusion criteria

CRPS-1 or other condition on contralateral extremity, asthma, cardiac problems, hyperthyroidism, epilepsy, parkinson, kydney dysfunction, severe psychiatric dysfunction, history of digestive tract operation or ulcers, active malignant disease, other chronic pain syndrome, use of anti-cholinergic medication.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1586
NTR-old	NTR1666
Other	WC : 2008-106
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A