Iontophoretic administration of S(+)-ketamine in patients with neuropathic pain

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON36563

Source
ToetsingOnline

Brief title
SKIN study

Condition

- Peripheral neuropathies

Synonym
nerve pain, neuropathic pain

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: eigen budget

Intervention

Keyword: iontophoresis, ketamine, neuropathic pain

Outcome measures

Primary outcome

- overall pain relief. Measurement of pain intensity using a VAS-score

Secondary outcome

impact of S(+)-ketamine treatment on quality of life

impact of S(+)-ketamine treatment on health status(Pain disability index)

impact of S(+)-ketamine treatment on symptoms of neuropathic pain

Study description

Background summary

The effective treatment of patients suffering from peripheral neuropathic pain remains a clinical challenge (Mersey and Bogduk, 1994). Despite a standard pharmacological approach (stepwise escalation of the WHO analgesic ladder including opioids) in combination with first and second-line drugs such as anticonvulsants, antidepressants, baclofen, α-adrenergic agonists, and oral anesthetic antiarrhythmic agents, some of these patients experience severe neuropathic pain.
In these patients, iontophoretic administration of S(+)-ketamine has to be considered to decrease the neuropathic pain

Study objective

At this time, iontophoretic administration of S(+)-ketamine is a already in use as a treatment of peripheral neuropathic pain in several pain clinics In the Netherlands (including the pain clinic at the Medical Center in Alkmaar). Although this treatment is considered to be a valuable alternative, no scientific evaluation has been performed regarding its efficacy. Additionally, there is no knowledge available regarding a dose response curve.
The purpose of this randomized, double-blind, placebo controlled, crossover study is to investigate the benefits regarding pain relief, health status, and quality of life after administration of S(+)- ketamine by an iontophoresis-assisted transdermal drug delivery system in patients with

peripheral neuropathic pain. In this study several doses of S(+)-ketamine (i.e. placebo or 0 mg, 50 mg , 75 mg, and 100 mg S(+)-ketamine) will be evaluated.

Study design

Moncenter investigation
Randomized, double-blind, placebo controlled, crossover study

Intervention

This trial will be conducted following a complete counterbalancing design. Each patient will be treated with four different doses of S(+)-ketamine (0, 50, 75, and 100 mg) in a random treatment sequence. All possible treatment sequences will be present within the study group.
Because 4 different doses will be evaluated, a total of 24 treatment sequences are possible (4*3*2=24). In this view, 24 patients are necessary to perform this study. With an estimated dropout of 15%, a total of 28 patients will be randomized.
In this trial design, complete counterbalancing design, each patient will function as his own control. The main advantage of this trial design is that possible influences coming from suggestion or expectations by the patient will be neutralized. Between treatments, a washout period of minimal two weeks will be established.

Study burden and risks

Burden
Four treatments with different doses of S(+)-ketamine with 2 weeks interval between two treatments. The trial will take 8 weeks. Before start of treatment, patients will be evaluated using several questionnaires (30-45 minutes). Pain intensity using a Pain diary: 5 minutes per day
Questionnaires and a neurological clinical examination of the patients before each treatment: 30 minutes.
After each treatment: questionnaire (5 min) and a neurological clinical examination (10 min).
One day following each treatment< three questionnaires: 20 min.

Risks

Ketamine is primarily in use as an anestheticum. The parenteral use of ketamine may induce an increase in blood pressure and heart rhythm. In this trail S(+)-ketamine will be given to treat neuropathic pain. In this context, the dose is much lower and given through the skin using iontophoresis. The risks of side effects are very low. It is, however, always possible that side effects, as mentioned, may occur.
Possible side effects of S(+)-ketamine following parenteral administration are

decline in mood, conscious perception,
and intellectual performance, nightmares, and dizziness. No side effects, however, occur following iontophoretic administration of S(+)-ketamine in patients with central neuropathic pain.
Side effects are reversible and disappear after ending treatment with S(+)-ketamine

Benefit
Iontophoretic administration of S(+)-ketamine may relief neuropathic pain. In this view, patients may experience less pain following this treatment.

Contacts

Public
Medisch Centrum Alkmaar

wilhelminalaan 12,
1815 JD Alkmaar
NL
Scientific
Medisch Centrum Alkmaar

wilhelminalaan 12,
1815 JD Alkmaar
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients with neuropathic pain (more than 6 months present) as defined by the IASP
Pain detect score > 18 and pain intensity VAS score > 6and the presence of Allodynia (VAS score >4)
age between 18 and 75
written informed consent

Exclusion criteria

pregnancy
known hypersensitivity towards S(+)-ketamine
patients with psychiatric history or under treatment
patients with Angina pectoris, acute myocardial infarction, heart failure, heart rhythm disorder
patients with a pacemaker and/or an implantable cardioverter defibrillator
patients with uncontrollable arterial hypertension
patients with glaucoma
patients with uncontrollable thryroid dysfunction
Hospital Anxiety and Depression Scale (HADS-NL) score > 8 for depression and/or > 8 for anxiety
No new analgesic treatment may be initiated 6 weeks before start of the study
No change in analgesic treatment may be performed during the trial

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Will not start

Start date (anticipated):	01-09-2011
Enrollment:	28
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	ketanest
Generic name:	s-ketamine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	07-11-2011
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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
EudraCT	EUCTR2010-024514-62-NL
CCMO	NL34410.094.11