Intrathecal methylprednisolone for intractable postherpetic neuralgia.

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To measure the effectiveness of intrathecal methylprednisolone and lidocaine on reducing PHN. Measurement of mthylprednisolone concentrations in cerebrospinal fluid (Part I only).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON31764

Source
ToetsingOnline

Brief title
STIP (STeroids for Intractable Postherpetic neuralgia).

Condition

- Spinal cord and nerve root disorders

Synonym
Zoster Associated Pain. A garb of roses from hell.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: intractable, intrathecal, methylprednisolone, postherpetic neuralgia

Outcome measures

Primary outcome

Global pain relief 1 year after treatment tested by VAS scores.

Secondary outcome

Global pain relief at the end of treatment and after 4 weeks, 8 weeks, 6 months and 2 years.

VAS scores for burning and lancinating pain, and allodynia at the end of treatment and at each follow-up visit.

Areas of pain and allodynia at at the end of treatment and at each follow-up visit.

Methylprednisolone concentrations in cerebrospinal fluid. (Part I)

Interleukin-8 concentrations in cerebrospinal fluid.

EQ5D scores just before treatment and at each follow-up visit.

The amount of rescue medication used.

Side-effects.

Study description

Background summary

Postherpetic neuralgia (PHN) is a neuropathic pain disorder that affects mostly the elderly and which is often refractory to currently available treatments. Many patients suffer severe physical and social disabilities as a consequence of their chronic pain. One randomized controlled trial was published in which intrathecal administration of methylprednisolone proved an effective and safe treatment for intractable PHN. However, because of potential side effects and lack of replication of the trial this treatment is not generally accepted. Additional data are required to validate these promising results. Pharmacokinetic data of intrathecal administered methylprednisolone are

lacking.

Study objective

To measure the effectiveness of intrathecal methylprednisolone and lidocaine on reducing PHN.
Measurement of mthylprednisolone concentrations in cerebrospinal fluid (Part I only).

Study design

This is a monocenter, randomised, double-blind controlled trial with a 2 year follow-up period.

Intervention

For 2 weeks (the prestudy period) patients are treated with paracetamol and NSAIDs. During this period (and afterward) concomitant PHN medication maintained on a stable dose is allowed. After this period study drugs are injected into the lumbar intrathecal space once a week for 4 subsequent weeks by an experienced anesthesiologist.

The study consist of two parts. The first 10 patients will be included in part I, the remaining patients in part II.

Part I:
The index group will receive injections with 60 milligram methylprednisolone and 60 milligram lidocaine, the placebo group will receive 60 milligram of lidocaine. The potential neurotoxic preservatives are removed from the methylprednsiolone. Just before each injection samples of cerebrospinal fluid are obtained in all patients. Also, 1, 4 and 8 weeks after the last injection samples of cerebrospinal fluid will be taken from the index group. To remain blinding of the subjects, patients in the placebo group will receive a subcutaneous sham-puncture (not perforating the dura) at 1, 4 and 8 weeks after the last injection. Pain is evaluated at randomisation, before the first spinal injection, before the fourth spinal injection and then 4 weeks, 8 weeks, 6 months, 1 year and 2 years after the end of treatment. The EQ5D questionnaire will be used to evaluate the subject's perception of the general quality of life.

After Part I an interim analysis will be done on the pharmacokinetic data. When appropriate, adjustments will be made for patients included in Part 2 of the study.

Deel II:
The index group will receive injections with 60 milligram methylprednisolone

and 60 milligram lidocaine, the placebo group will receive 60 milligram of lidocaine. The potential neurotoxic preservatives are removed from the methylprednsiolone. Just before each injection samples of cerebrospinal fluid are obtained in all patients. Pain is evaluated at randomisation, before the first spinal injection, before the fourth spinal injection and then 4 weeks, 8 weeks, 6 months, 1 year and 2 years after the end of treatment. The EQ5D questionnaire will be used to evaluate the subject's perception of the general quality of life.

Study burden and risks

We are planning to offer this new treatment to this group of patients who have no other treatment options left. We prefer to do so in a research setting for above mentioned reasons (see section E9a).
Spinal anesthesia is a routine procedure that is used millions of times each year. It is safe and rarely associated with neurologic complications [1].
The burden for the subjects in the index group in Part I will be 3 additional punctions for obtaining cerebrospinal fluid. The other subjects in Part I of the study will receive three placebo punctions in which the needle will be introduced through the subcutaneous tissues to the intraspinal ligaments, without perforation of the dura.
The risks associated with intrathecal punctions when using a 25 Gauge pencil-point needle by an experienced anesthesiologist are very small. Many patients report that a spinal injection is less painfull than a venapuncture.

[1] Horlocker et al. A retrospective review of 4767 consecutive spinal anesthetics: central nervous system complications. Anesth Analg 1997; 84: p. 578-84.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Adult outpatients with a history of postherpetic neuralgia (PHN) for at least 6 months after onset of the vesicular eruption.
-Global pain intensity at least 40 mm on a 100 mm visual-analogue scale (VAS) despite conventional therapy.

Exclusion criteria

-PHN in regions innervated by the trigeminal nerve.
-Polyneuropathy or severe other neurologic disease.
-Diseases accompanied with an immunocompromised state.
-Disorders of coagulation (including use of coumarin anticoagulants).
-Contra-indications for spinal anesthesia.
-Satisfactory pain relief with conventional treatments(s).
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Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2008
Enrollment:	42
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Depo-Medrol
Generic name:	methylprednisoloneacetate
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	hyperbaric lidocaine 2%
Generic name:	hyperbaric lidocaine 2%
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-02-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-09-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2008-000690-37-NL
CCMO	NL18867.041.07