Intrathecal methylprednisolone for intractable postherpetic neuralgia.

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To measure the effectiveness of intrathecal methylprednisolone and lidocaine on reducing postherpetic neuralgia. Measurement of intrathecal methylprednisolone concentrations.

Ethical review	Not approved
Status	Will not start
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON30745

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,Vooralsnog eerste geldstroom (budget DPAP). Een subsidie aanvraag bij EFIC Grunenthal is ingediend. Een subsidie bij NWO wordt ingediend.

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

-Methylprednisolone concentrations in liquor.

-interleukin-8 concentrations in liquor.

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

-The amount of used rescue medication.

-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 to be 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 postherpetic neuralgia.
Measurement of intrathecal methylprednisolone concentrations.

Study design

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

Intervention

For 4 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. The index group will receive intrathecal injections with 60 milligram methylprednisolone and 60 mg lidocaine, the placebo group will receive 60 milligrams of lidocaine. The potentially neurotoxic preservatives are removed from the methylprednisolone. Before the each injection and 1,4 and 8 weeks after the last injection samples of cerebrospinal fluid are obtained for methylprednisolone concentration testing. Pain is evaluated at randomisation, before the first spinal injection, before the fourth 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. We prefer to do so in a research setting for above mentioned reasons (see section E9a). The burden for the patient will be 3 additional intrathecal puncions for obtaining cerebrospinal fluid.
Spinal anesthesia is a routine procedure that is used millions of times each year. It is safe and rarely associated with neurologic complications [1].

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

[2] Santanen et al. Comparison of 27-gauge Whitacre and Quincke spinal needles with respect to post-dural puncture headache and nondural pncture headachte. Acta anaesthesiol scand 2004;48:474-479.

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 100 mm visual-analogue scale (VAS) despite conventional therapies.

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 treatment(s).

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:	Will not start
Enrollment:	42
Type:	Anticipated

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:	lidocaine 2%
Generic name:	lidocaine 2%

Registration:	Yes - NL intended use

Ethics review

Not approved

Date:	01-05-2007
Application type:	First submission
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	EUCTR2006-002967-17-NL
CCMO	NL11411.041.06