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# Intrathecal steroids for intractable postherpetic neuralgia

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 11/11/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 19/02/2009 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 31/03/2010 | Infections and Infestations | [_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## Study information

**Scientific Title**
Intrathecal steroids for intractable postherpetic neuralgia: a randomised controlled trial

**Acronym**
STIP

**Study objectives**
Intrathecal administration of methylprednisolone with lidocaine is more effective than lidocaine alone in the reduction of pain in postherpetic neuralgia (PHN).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
To be submitted as of 11/11/2008

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Postherpetic neuralgia

## Interventions
Administration of 60 mg lidocaine (intrathecal) with or without 60 mg methylprednisolone (intrathecal).

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
Global pain relief at 1-year follow-up.

## Key secondary outcome(s)
1. Global pain relief at the end of treatment and after 4 weeks, 8 weeks, 6 months and 2 years follow-up
2. Reduction of VAS scores for global, burning and lancinating pain, and allodynia at the end of treatment and after 4 weeks, 8 weeks, 6 months, 1 year and 2 years follow-up
3. Reduction of areas of pain and allodynia at the end of treatment and after 4 weeks, 8 weeks, 6 months, 1 year and 2 years follow-up
4. Reduction in mean number of paracetamol tablets consumed per week at the end of treatment and after 4 weeks follow-up
5. Reduction in mean percentage of the maximal dose of NSAIDs used per week at the end of treatment and after 4 weeks follow-up
6. Reduction in the percentage of the initial dose(s) of PHN medication at the end of treatment and after 4 weeks follow-up
7. Euroqol EQ-5D scores just before treatment and at 4 weeks, 8 weeks, 6 months, 1 year and 2 year follow-up visits

## Completion date
01/12/2010

# Eligibility

### Key inclusion criteria
1. Outpatient, male or female, aged 18 years or older
2. History of PHN for at least 6 months after onset of the vesicular eruption
3. Global pain intensity due to PHN must be at least 40 mm on 100 mm Visual Analogue Scale (VAS) for the last 24 hours despite conventional therapies, as recorded at Visit 1
4. The PHN must be restricted to the dermatomes involved in the original eruption of herpes zoster
5. Patient does not use concomitant medication for PHN, or is using concomitant PHN medication on a stable dose for at least 4 weeks prior to randomisation
6. Patients must be willing and able to give informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
1. PHN in regions innervated by the trigeminal nerve
2. Previous neurolytic or neurosurgical treatment for PHN (radiofrequency neuroablation [RF] treatment of the dorsal root ganglion is allowed)
3. Patients who have other pain, which could confound the assessment of the neuropathic pain due to PHN
4. Patients with polyneuropathy or other severe neurologic disease (e.g., multiple sclerosis)
5. Patients with diseases accompanied with a severe immunocompromised state (e.g., during chemotherapy, AIDS; HIV is not an exclusion criterion)
6. Use of coumarin anticoagulants
7. Contra-indications for spinal anaesthesia
8. Contra-indications for oral non-steroidal anti-inflammatory drug (NSAID) use
9. Satisfactory pain relief with conventional treatment (including at least one trycyclic antidepressant and at least one anti-epileptic)
10. Adjustments in concomitant PHN medication during the past 4 weeks
11. Previous spinal anaesthesia with steroids for PHN
12. Skin conditions in the area affected by the neuralgia that could alter sensation
13. Clinically significant psychiatric diagnoses, in particular depression, that would impair their reliable participation in this trial
14. Body Mass Index (BMI) >35 kg/m^2
15. Woman of childbearing potential who is not willing or unable to take adequate birth control measures during the study and for at least 6 months after the last injection

16. Pregnant patients and women who are lactating
17. Problems with communication (language, deafness, aphasia)

**Date of first enrolment**
01/12/2008

**Date of final enrolment**
01/12/2010

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**University Medical Centre Utrecht**
Utrecht
Netherlands
3508 GA

# Sponsor information

**Organisation**
University Medical Centre Utrecht (UMCU), Department of Perioperative Care and First Aid (DPenS) (Netherlands)

**ROR**
https://ror.org/04pp8hn57

# Funder(s)

**Funder type**
University/education

**Funder Name**
University Medical Centre Utrecht (UMCU), Department of Perioperative Care and First Aid (DPenS) (Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration