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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Global pain relief at 1-year follow-up.

Secondary outcome measures
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

Overall study start date
01/12/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

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)

Sponsor details
Postbus 85500
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Sponsor type
University/education

Website
http://www.umcutrecht.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration