

Intrathecal steroids for intractable postherpetic neuralgia

Submission date
11/11/2008

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
19/02/2009

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
31/03/2010

Condition category
Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr A J M van Wijck

Contact details

University Medical Centre Utrecht
Postbus 85500
Utrecht
Netherlands
3508 GA

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 tricyclic 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) $>35 \text{ kg/m}^2$
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
Utrecht
Netherlands
3508 GA

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