

Efficacy and safety of gabapentin versus placebo to prevent the incidence of postherpetic neuralgia

Submission date 29/01/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/05/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/06/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Postherpetic neuralgia is thought to be nerve damage caused by herpes zoster virus. The damage causes nerves in the affected area of the skin to send abnormal electrical signals to the brain. The aim of this study is to analyse the efficacy of a drug gabapentin in patients 50 years old or above with moderate to severe pain during the acute phase of the herpes zoster in the prevention of the postherpetic neuralgia. The study's findings should help to reduce the percentage of patient that show postherpetic neuralgia during an episode of herpes zoster.

Who can participate?

Men and women aged 50 or above diagnosed or uncomplicated Herpes zoster within 72 hours of onset of the rash in patients with acute herpes zoster and with moderate/severe pain.

What does the study involve?

Participants are randomly allocated to take either gabapentin or placebo (dummy drug) for 5 weeks. At the end of the study, the prevalence of postherpetic neuralgia is compared in the placebo and gabapentin groups.

What are the possible benefits and risks of participating?

Gabapentin is an drug authorised by the European and American drugs agencies for the treatment of epilepsy and postherpetic neuralgia, both agencies has evaluated the safety of the gabapentin for the treatment of epilepsy and is not expected to be less safer in those patients with Herpes zoster. Patients treated with gabapentin for 5 weeks in the acute herpes zoster period plus valacyclovir and analgesic will reduce the incidence of postherpetic neuralgia by 25% compared to placebo.

Where is the study run from?

Primary Care Management of Mallorca

When is the study starting and how long is it expected to run for?

May 2013 to November 2015.

Who is funding the study?
Institute of Health Carlos III (Spain)

Who is the main contact?
Manel Rullán
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI12_01813

Study information

Scientific Title
Efficacy and safety of gabapentin versus placebo to prevent the incidence of PostHerpetic Neuralgia: a double-blinded clinical trial

Acronym
PHN

Study objectives
Patient treated with gabapentin for 5 weeks in the acute herpes zoster period plus valacyclovir and analgesic will reduce the incidence of postherpetic neuralgia by 25% when compared to placebo plus valacyclovir and analgesic.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Illes Balears ethics committee - approval pending

Study design

Phase III multi-centre double-blind placebo randomized clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Postherpetic neuralgia

Interventions

Antiviral therapy is first-line treatment and should be initiated within 72 hours of rash onset to increase the rate of healing and decrease pain, valacyclovir is also effective in the prevention of the postherpetic neuralgia, placebo and gabapentin groups will receive 1g/8h the first week.

Pain management: The WHO three-step "ladder" will be used for pain management. If pain occurs, there should be prompt oral administration of drugs in the following order: non opioids (aspirin and paracetamol); then, as necessary, mild opioids (codeine); then strong opioids such as morphine, until the patient is free of pain.

Gabapentin or placebo treatment: effective dose should be individualized according to patient response and tolerability. The treatment should be started at a dose of 900 mg/d (300 mg/d on day 1, 600 mg/d on day 2, and 900 mg/d on day 3), then every 2 or 3 day an increase of 300mg depending up to a maximum doses of 3600mg/day. The treatment will end at 5 weeks, in the last week gabapentin or placebo will be gradually tapered.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Gabapentin, valacyclovir

Primary outcome measure

Prevalence of postherpetic neuralgia, assessed using the Visual Analog Scale (VAS >0) at 12 weeks

Secondary outcome measures

1. Prevalence of postherpetic neuralgia, assessed using the Visual Analog Scale (VAS >0) at 6 weeks
2. Percentage of patients with a reduction of at least 50% in the VAS scale

Overall study start date

15/05/2013

Completion date

15/11/2015

Eligibility

Key inclusion criteria

1. Patient aged 50 or above, either sex
2. Patient diagnosed or uncomplicated herpes zoster within 72 hours of onset of the rash in patients with acute herpes zoster and with moderate/severe pain (Analogic visual scale ≥ 4)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

254 patients

Total final enrolment

98

Key exclusion criteria

1. Patients taking gabapentin
2. Patients diagnosed of severe hepatic impairment, hypersensitivity to gabapentin or excipients, acute renal failure or renal impairment ($\text{Clcr} < 79 \text{ ml/min}$)
3. Patients with evidence of cutaneous or visceral dissemination of herpes zoster infection (cutaneous dissemination is defined as 20 discrete lesions outside adjacent dermatomes) or ocular dissemination
4. Immunocompromised state and/or interferon treatment in the last 4 weeks
5. Patient taking tricyclic antidepressants or corticoids in the inclusion or treatment period

Date of first enrolment

15/05/2013

Date of final enrolment

15/11/2015

Locations

Countries of recruitment

Spain

Study participating centre

Centro de Salud de Pollença; C/ BISBE DESBACH, S/N

Pollença

Spain

07460

Sponsor information

Organisation

Primary Care Management of Mallorca (Gerencia de Atención Primaria de Mallorca) (Spain)

Sponsor details

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Sponsor type

Government

Website

<http://www.caib.es/govern/organigrama/area.do?coduo=1296290&lang=ca>

ROR

<https://ror.org/00d9y8h06>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Instituto de Salud Carlos III (ref: PI12_01813)

Alternative Name(s)

SaludISCI, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/01/2017		Yes	No
Results article	results	05/06/2019	06/06/2019	Yes	No