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

Submission date
29/01/2013

Recruitment status
No longer recruiting

Registration date
02/05/2013

Overall study status
Completed

Last Edited
06/06/2019

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

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

Study type(s)
Prevention

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

Key secondary outcome(s)
1. Prevalence of postherpetic neuralgiaa, 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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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 (Clcr <79ml/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)

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)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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