# Neuragen® for the relief of neuropathic pain: a randomised, double-blind, placebo controlled clinical trial

| Submission date   | Recruitment status  No longer recruiting | Prospectively registered    |  |  |
|-------------------|--|-----------------------------|--|--|
| 09/06/2008        |  | ☐ Protocol                  |  |  |
| Registration date | Overall study status                     | Statistical analysis plan   |  |  |
| 13/06/2008        | Completed                                | [X] Results                 |  |  |
| Last Edited       | Condition category                       | Individual participant data |  |  |
| 25/05/2010        | Nervous System Diseases                  |                             |  |  |

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Li Li

#### Contact details

Department of Kinesiology Louisiana State University Baton Rouge United States of America 70803

# Additional identifiers

**Protocol serial number** N/A

# Study information

Scientific Title

**Study objectives** 

Neuragen® reduces neuropathic pain more and longer than placebo.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Institutional Review Board of Louisiana State University as an extension of IRB#2754, approved on 28th September 2007.

## Study design

Randomised, double-blind, placebo controlled clinical trial

#### Primary study design

Interventional

# Study type(s)

**Treatment** 

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

Peripheral neuropathy

#### **Interventions**

Topical application of Neuragen® versus placebo. The medicine was sprayed onto the subjects feet at the sole and on top of the feet. One time application with an 8-hour follow-up.

## Intervention Type

Drug

#### Phase

**Not Specified** 

# Drug/device/biological/vaccine name(s)

Neuragen®

## Primary outcome(s)

Foot sole pain on 11-point numerical pain scale. 0 - 10 visual analog scale was use to document pain level at 30 minutes before and after the administration of the medication, with 8-hour follow up every hour on the hour.

# Key secondary outcome(s))

Duration of pain reduction. 0 - 10 visual analogue scale was use to document pain level at 30 minutes before and after the administration of the medication, with 8-hour follow up every hour on the hour.

## Completion date

30/04/2008

# Eligibility

# Key inclusion criteria

- 1. Male and female, over 21 years
- 2. Diagnosed neuropathic pain for more three months
- 3. Pain level between 3 8 on a 0 10 visual pain scale
- 4. Does not have mental and communication impairments

# Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

# Key exclusion criteria

- 1. Pregnant
- 2. Have other types of pain
- 3. Skin condition
- 4. Central nerve impairment

#### Date of first enrolment

01/01/2008

#### Date of final enrolment

30/04/2008

# Locations

#### Countries of recruitment

United States of America

# Study participating centre Department of Kinesiology

Baton Rouge United States of America 70803

# Sponsor information

## Organisation

Origin BioMed, Inc. (Canada)

#### **ROR**

https://ror.org/008mcnd42

# Funder(s)

# Funder type

Industry

## Funder Name

Origin BioMed, Inc. (Canada)

# **Results and Publications**

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? |
|-------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| Results article               | results                       | 20/05/2010   |            | Yes            | No              |
| Participant information sheet | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |