

Neuragen® for the relief of neuropathic pain part 2: a randomised, double-blind, placebo controlled clinical trial

Submission date 09/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/06/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/06/2008	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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® with a different amount of effective ingredients will reduce neuropathic pain more than the placebo whilst having different levels of effectiveness.

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® with different amounts of effective ingredients versus a 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 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.

Completion date

27/09/2008

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

19/05/2008

Date of final enrolment

27/09/2008

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