

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

19/05/2008

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

Age group

Adult

Sex

Both

Target number of participants

60

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)

Sponsor details

5162 Duke St, Suite 300

Halifax

Canada

B3J 1N7

Sponsor type

Industry

Website

<http://www.originbiomed.com/>

ROR

<https://ror.org/008mcnd42>

Funder(s)

Funder type

Industry

Funder Name

Origin BioMed, Inc. (Canada)

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