

The effect of Neuragen® on neuropathic pain: Double-blind, placebo-controlled clinical trial

Submission date 04/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/06/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/08/2011	Condition category Nervous System Diseases	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives

Neuragen® reduces neuropathic pain more than placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board, Louisiana State University. Date of approval: 09/28/2007 (ref: 2754)

Study design

Double-blind, randomised, placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

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® vs placebo. Neuragen®/placebo is applied once each in random order and in a double-blind fashion. The applications are at least one week apart from each other. Pain is measured 30 minutes before and after the application, and tracked every hour for 8 hours.

Total duration of follow-up: 8 hours after each application

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Foot sole pain on 11-point numerical pain scale, measured 30 minutes before and after the Neuragen®/placebo application, and tracked every hour for 8 hours.

Secondary outcome measures

Duration of pain reduction. Pain is measured 30 minutes before and after the application, and tracked every hour for 8 hours.

Overall study start date

01/10/2007

Completion date

27/09/2008

Eligibility

Key inclusion criteria

1. Both males and females, over 21
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

01/10/2007

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 Street
Suite 300
Halifax
Canada
B3J 1N7

Sponsor type

Industry

Website

<http://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