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

Submission date 04/06/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 09/06/2008	**Overall study status** Completed	
Last Edited 16/08/2011	**Condition category** Nervous System Diseases	

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 form 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