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

Submission date
04/06/2008

Registration date
09/06/2008

Last Edited
16/08/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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)

Primary study design
Interventional

Study design
Double-blind, randomised, placebo-controlled trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
Duration of pain reduction. Pain is measured 30 minutes before and after the application, and tracked every hour for 8 hours.

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

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
01/10/2007

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)

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