ISRCTN13226601 https://doi.org/10.1186/ISRCTN13226601

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

Submission date
09/06/2008

Recruitment status
No longer recruiting

Registration date
13/06/2008

Overall study status
Completed

Last Edited
25/05/2010

Condition category
Nervous System Diseases

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

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® reduces neuropathic pain more and longer than placebo.

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® versus 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 analogue 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
01/01/2008

Completion date
30/04/2008

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
01/01/2008

Date of final enrolment
30/04/2008

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://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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/05/2010		Yes	No