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Neuragen® gel versus placebo in the relief of neuropathic foot pain

Submission date	Recruitment status	[X] Prospectively registered
01/11/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/11/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/11/2009	Nervous System Diseases	[ ] 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
32438

Study information

Scientific Title
The effectiveness of Neuragen® gel versus placebo in the relief of neuropathic foot pain: a double-blind randomised placebo-controlled clinical trial

Study objectives
Neuragen® gel is more effective in relieving neuropathic foot pain than placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Louisiana State University approved on the 15th September 2009 (ref: 2754)

Study design
Double-blind randomised placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details provided to request a patient information sheet

Health condition(s) or problem(s) studied
Peripheral neuropathy

Interventions
This is a double blind randomised clinical trial. The company pre-packages the treatments in two identical containers labeled A and B; each contains one application of the topical Neuragen® gel and placebo. A or B will be applied to the foot sole of the participants only once each, at least seven days apart between the two applications. Foot pain will be recorded 30 minutes before, 30 minutes after and every hour on the hour for up to 8 hours.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Neuragen® gel

Primary outcome measure
Level of pain on a 0 - 10 visual pain scale, measured 30 minutes before and after the application of of the treatment, and every hour thereafter for 8 hours.

Secondary outcome measures
Duration of pain reduction, measured on a 0 - 10 visual pain scale which will be used every hour on the hour for up to 8 hours.

Overall study start date
09/11/2009

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. Male and female aged over 21 years
2. Diagnosed with neuropathic pain more 3 months
3. Pain level between 5 - 9 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 impairments

Date of first enrolment
09/11/2009

Date of final enrolment
31/10/2010

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
5126 Duke Street
Suite 300
Halifax
Canada
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mclellan@originbiomed.com

Sponsor type
Industry

Website
http://www.originbiomed.com/canada-en/

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