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

Contact name

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Contact details

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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 B3J 1N7 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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration