

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

Submission date 01/11/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/11/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
112 Long Field House
Baton Rouge
United States of America
70803
lli3@lsu.edu

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

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 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)

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