

Neuract® cream versus placebo in the relief of neuropathic lower back pain

Submission date 30/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/07/2010	Condition category Musculoskeletal 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
Li Li, Ph.D.
Department of Kinesiology
Louisiana State University
112 Long Field House
Baton Rouge
United States of America
70803
lli3@lsu.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32440

Study information

Scientific Title

The effectiveness of Neuract® cream versus placebo in the relief of neuropathic lower back pain: a double-blind randomised placebo-controlled clinical trial

Study objectives

Neuract® is more effective in relieving neuropathic lower back pain than placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board (IRB), Louisiana State University approved on the 22nd of March 2010 (ref: 2760)

Study design

Double blind randomized 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

Neuropathic lower back pain

Interventions

Patients will be randomised to receive a topical dose of Neuract® or placebo.

For each treatment arm, a pre-packaged single dose, approximately 1ml, will be applied. The pain reduction effects will be monitored starting 30 minutes after the application, up to 8 hours. Both the actual treatment and the placebo will be used only once and pain reduction effects compared to baseline pain measured 30 minutes before the treatment application.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Neuract® cream

Primary outcome measure

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

Secondary outcome measures

Duration of pain reduction

Overall study start date

14/06/2010

Completion date

31/12/2010

Eligibility**Key inclusion criteria**

1. At least 21 years old
2. Diagnosed with neuropathic lower back pain for at least 3 months
3. Pain at or more than level 5 but no more than 9 on a 0-10 scale
4. Score at least 6 of 10 on the modified DN4 questionnaire
5. Normal cognitive and communication skills

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Pregnant, breastfeeding or planning on becoming pregnant in the next 3 months
2. Previous adverse reaction to use of topical analgesic
3. Current use of topical analgesic on lower back area
4. Evidence of other types of pain as, or more severe, than the pain under study
5. Diagnosis of psychological disorder requiring treatment
6. History of eczema/atopy/anaphylaxis or unusual skin reactions
7. Self reported sensitivity to perfumes, essential oils, odors
8. Changes to current pain management regime within the previous 30 days prior to start of study

Date of first enrolment

14/06/2010

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

United States of America

Study participating centre

Li Li, Ph.D.

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

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