

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

|                                        |                                                       |                                                      |
|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>30/05/2010   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                       | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>14/07/2010 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                       | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>19/07/2010       | <b>Condition category</b><br>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

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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s)**

Duration of pain reduction

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

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# 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