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

Submission date	Recruitment status	[ ] Prospectively registered
30/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/07/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/07/2010	Musculoskeletal 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

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)

Primary study design
Interventional

Study design
Double blind randomized placebo controlled clinical trial

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 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