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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

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 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