Nexalin Therapy for the Treatment of Depressive Symptoms

This study has been completed.
First Received: July 3, 2008  Last Updated: October 16, 2008  History of Changes
Sponsored by: Kalaco Scientific, Inc.
Information provided by: Kalaco Scientific, Inc. ClinicalTrials.gov Identifier: NCT00774813

Purpose
The primary objectives of this Phase II study are to demonstrate the safety of Nexalin Therapy and to investigate the efficacy of Nexalin Therapy.

Condition Intervention Phase
Depression
Device: Nexalin 1.3mA Device
Device: Nexalin 15mA device
Drug: placebo device and Citalopram
Phase II

MedlinePlus related topics: Anxiety Depression
Drug Information available for: Benzetimide Dextetimide Citalopram hydrobromide Citalopram Escitalopram Escitalopram oxalate
U.S. FDA Resources

Study Type: Interventional
Study Design: Treatment, Randomized, Double Blind (Subject, Caregiver, Investigator), Placebo Control, Parallel Assignment, Safety/Efficacy Study

Official Title: Phase II Study Using Nexalin Therapy for the Treatment of Depressive Symptoms Associated With Mild to Moderate Depression Episodes

Further study details as provided by Kalaco Scientific, Inc.: 

Primary Outcome Measures:
Hamilton Depression Rating Scale (HAM-D21) [ Time Frame: Screening; Baseline; Treatments 5, 10, & 15; Follow-up Weeks 2, 4, 8, & 12 ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
Clinical Global Impression (CGI) [ Time Frame: Screening; Baseline; Treatments 5, 10, & 15; Follow-up Weeks 2, 4, 8, & 12 ] [ Designated as safety issue: No ]
Montgomery-Asberg Depression Rating Scale (MADRS) [ Time Frame: Screening; Baseline; Treatments 5, 10, & 15; Follow-up Weeks 2, 4, 8, & 12 ] [ Designated as safety issue: No ]
Beck's Depression Inventory [ Time Frame: Screening; Baseline; Treatments 5, 10, & 15; Follow-up Weeks 2, 4, 8, & 12 ] [ Designated as safety issue: No ]
Hamilton Anxiety Rating Scale (HAM-A) [ Time Frame: Screening; Baseline; Treatments 5, 10, & 15; Follow-up Weeks 2, 4, 8, & 12 ] [ Designated as safety issue: No ]
Hospital Anxiety and Depression Scale (HADS) [ Time Frame: Screening; Baseline; Treatments 5, 10, & 15; Follow-up Weeks 2, 4, 8, & 12 ] [ Designated as safety issue: No ]
Medication Usage Log [ Time Frame: Every visit ] [ Designated as safety issue: No ]
Adverse Event Log [ Time Frame: Every visit ] [ Designated as safety issue: Yes ]

Enrollment: 120
Study Start Date: October 2007
Study Completion Date: May 2008
Primary Completion Date: May 2008 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>A: Active Comparator</td>
<td>Device: Nexalin 1.3mA Device 3 treatment cycles (cycle is 5 daily treatments, followed by 2 days off) Daily receipt of placebo antidepressant</td>
</tr>
<tr>
<td>Nexalin 1.3mA device +</td>
<td>placebo antidepressant</td>
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<tr>
<td>placebo antidepressant</td>
<td></td>
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<tr>
<td>B: Active Comparator</td>
<td>Device: Nexalin 15mA device 3 treatment cycles (cycle is 5 daily treatments, followed by 2 days off) Daily receipt of a placebo antidepressant</td>
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<tr>
<td>Nexalin 15mA device +</td>
<td>placebo antidepressant</td>
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<td>placebo antidepressant</td>
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<tr>
<td>C: Placebo Comparator</td>
<td>Drug: placebo device and Citalopram 3 treatment cycles (cycle is 5 daily treatments, followed by 2 days off) Daily receipt of a SSRI (Citalopram or similar)</td>
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<tr>
<td>Placebo device + SSRI</td>
<td>(Citalopram or similar)</td>
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<tr>
<td>(Citalopram or similar)</td>
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Detailed Description:
This randomized, double-blind, placebo-controlled, multi-center trial has 3 different treatment arms.

Study Tools:
- Hamilton Depression Rating Scale (HAM-D21)
- Clinical Global Impressions (CGI)
- Montgomery-Asberg Depression Rating Scale (MADRS)
- Beck's Depression Inventory
- Hamilton Anxiety Rating Scale (HAM-A)
- Hospital Anxiety and Depression Scale (HADS)

Eligibility
- Ages Eligible for Study: 18 Years to 65 Years
- Genders Eligible for Study: Both
- Accepts Healthy Volunteers: No

Inclusion Criteria:
- Diagnosed with mild to moderate depression episode, based on the HAM-D21 Rating Scale (10-13 = mild; 14-17 = mild to moderate)
- Diagnosed with mild to moderate depression episode based on ICD-10 Diagnostic Guidelines
- Is willing and able to spend 4 weeks as a hospital inpatient
- Is willing and able to return to the clinic during follow-up period

Exclusion Criteria:
- A HAM-D21 Rating Scale of <10 or >17
- Diagnosed outside of mild to moderate depression episode range based on the ICD-10 Diagnostic Guidelines
- Unable to complete wash-out interval without taking antidepressants or psychotropic medications
- Is pregnant or may be pregnant
Sensitivity to electrodes and/or their conductive gels or adhesives
Break in skin integrity at the areas of electrode placement
Currently taking immune suppressing drugs or suspected use of narcotics

Presence of any implanted electronic devices, cardiac stimulator, or pacemaker
History of brain injury, including seizures, epilepsy, stroke, tumor of central nervous system, or hydrocephalus
History of heart attacks, congestive heart failure, or uncontrolled hypertension
History of schizophrenia or manic-depressive syndrome

Contacts and Locations
Please refer to this study by its ClinicalTrials.gov identifier: NCT00774813

Locations

Russian Federation

St. Petersburg City Center of Neuroses
St. Petersburg, Russian Federation, 191187

Russian Federation, Vsevolozhsky District
Leningrad Regional Center of Addiction
Leningrad, Vsevolozhsky District, Russian Federation, 188661

Sponsors and Collaborators
Kalaco Scientific, Inc.

Investigators
Principal Investigator: Evgeny Kruptisky, MD, PhD Leningrad Regional Center of Addiction

More Information

No publications provided
Responsible Party: Leningrad Regional Center of Addiction (Evgeny Kruptisky, MD, PhD)
Study ID Numbers: CPMS-7003
Study First Received: July 3, 2008
Last Updated: October 16, 2008
ClinicalTrials.gov Identifier: NCT00774813 History of Changes
Health Authority: United States: Institutional Review Board; Russia: Ministry of Health and Social Development of the Russian Federation

Keywords provided by Kalaco Scientific, Inc.:
Depression
Mild
Moderate
Anxiety
Kalaco Scientific, Inc.

Study placed in the following topic categories:
Neurotransmitter Agents Behavioral Symptoms
Depression Mental Disorders
Psychotropic Drugs Mood Disorders
Depressive Disorder Dexetimide
Citalopram  Antidepressive Agents, Second-Generation
Serotonin Uptake Inhibitors  Antidepressive Agents
Serotonin

Additional relevant MeSH terms:
Neurotransmitter Agents  Pharmacologic Actions
Neurotransmitter Uptake Inhibitors  Behavioral Symptoms
Depression  Serotonin Agents
Molecular Mechanisms of Pharmacological Action  Mental Disorders
Physiological Effects of Drugs  Therapeutic Uses
Psychotropic Drugs  Mood Disorders
Depressive Disorder  Antidepressive Agents, Second-Generation
Citalopram  Central Nervous System Agents
Serotonin Uptake Inhibitors  Antidepressive Agents

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