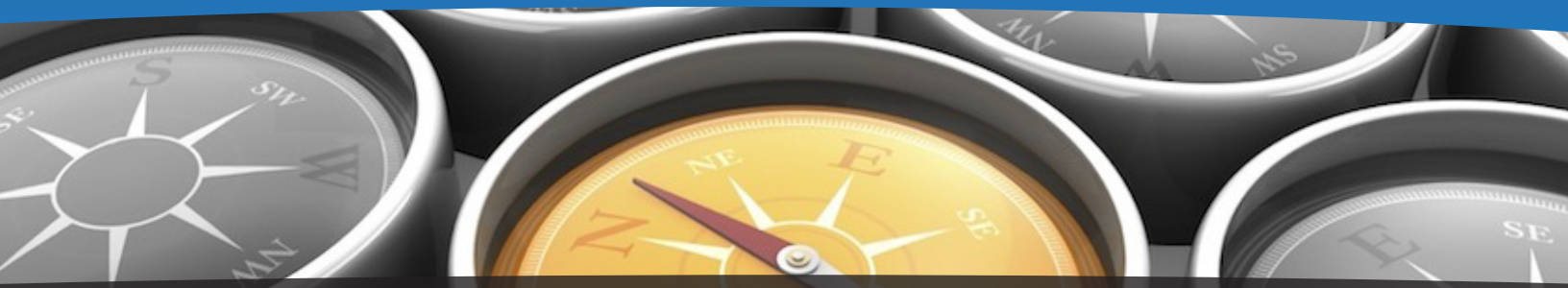
ACTIGRAPHY CORE LABORATORY CASE STUDY

CLINiLABS



A Double-Blind, Parallel Group, Randomized, Placebo Controlled Actigraphy Laboratory Study

Study Information

Clinical Phase	Phase II
Study Objectives	Test a safety and tolerability study to investigate the effect on sleep of 3 doses of XXXX and placebo in patients with mild Alzheimer's disease (AD) and Mild Cognitive Impairment (MCI).
Study Design	Double blind, multi-site, placebo controlled, randomized, parallel group study designed to objectively assess and quantify the effects on sleep induced by XXXX.
Study Populations	Male and female patients, aged 50-80, diagnosed with mild Alzheimer's disease (AD) or Mild Cognitive Impairment (MCI).
Study Duration:	4 Weeks (28 Days)
Number of Clinical Sites:	23
Enrollment:	Randomized: 72 Completed: 64

Clinilabs, a contract organization (CRO), was selected by a large, global pharmaceutical company to investigate the effect of 3 doses of XXXX and placebo on sleep in patients with mild Alzheimer's disease (AD) and Mild Cognitive Impairment (MCI). Study subjects were assessed using actigraphy, which is a non-invasive method of monitoring human activity and rest . For this study, Clinilabs utilized the Motionlogger actigraph, which is manufactured by our strategic partner, Ambulatory Monitoring, Inc.

The study population consisted of male and female patients between the ages of 50 and 80, and involved the participation of 23 clinical sites in the US. Investigator sites were pre-certified prior to the study start, and study personnel were provided training at the investigator meeting. A comprehensive manual was provided to each investigator site in order to assure uniformity in data collection and processing across all participating centers. A helpdesk was available 24 hours a day, seven days per week.

In this study, Motionlogger actigraphs were applied at baseline and worn throughout the study in order to obtain information about daytime activity, sleep, and agitation. Motionloggers are lightweight devices, very similar in size and weight to a common wrist watch. They are worn on the subject's non-dominant wrist, and collect data that can be used to measure activity both day and night. Extended periods of data collection lasting weeks at a time are feasible. Once the data collection is completed, data are transferred to Clinilabs' core laboratory using a simple Internet interface. Data are then scored centrally in order to provide standardized surrogate measures of key outcome variables.

One of the important features of this study involved the use of hospital-style wristbands to keep actigraphs in place during the recording period. This helped to ensure that datasets were complete. We also had positive feedback from investigator sites indicating that the devices were easy to use, well tolerated by subjects, and simple to operate for data transfer. We anticipated occasional loss or damage, so we kept a "back stock" of replacement units that could be shipped to investigator sites in less than 24 hours. We did not to utilize these units. The project succeeded with collection of actigraphy data for all 64 completers. Data quality was consistently high (ranked 5 on a 5-point scale), with no unreadable events or artifact.

CORE LAB

Clinilabs' core laboratories offer industry-leading operational expertise, physical and electronic security systems, and a high-performance network infrastructure to enable the centralized capture and processing of clinical trial data. The core laboratories provide clients with a turnkey solution for ECG, PSG, EEG, EMG, HST, actigraphy, PVT, and video data collection in clinical trials. We provide investigator site qualification, device management, study-wide SOPs, centralized data processing with rapid turnaround time, and a 24/7 helpdesk that support studies worldwide.

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