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Aloha!

It is not always easy for patients and families in Hawaii to travel to the mainland for the latest cutting edge research treatments considering the distance and time away from work and families for both patients and caretakers. Therefore, The Clinical Research Center at Hawaii Pacific Neuroscience has dedicated our effort and resources to bring world class ground breaking neuroscience research and clinical trials to our island state to serve an unmet neuroscience needs.

Principal Investigator (PI) Kore Liow, MD is an NIH trained neurologist with over 20 years of experience in clinical research and has served as PI for over 50 clinical trials in neuroscience sponsored by the industries, NIH, CDC and others and published over 40 peer reviewed articles in neuroscience. He dedicates over 60% of his time in research. He is supported by a team of 10 specialists and researchers consisting of neurologists sub specializing in Stroke, Parkinson's, Dementia, Headache, Neuromuscular & Pediatric Neurology, Geriatrician, Neuropsychologists and Psychologist.

Because of the support of the local community, our research and clinical trial program has grown to be one of the most sought after clinical trial site in the US for neuroscience conditions because of its reputation for excellence in clinical care and operational excellence in research. The clinical trial site has electronic database with close to 10,000 patients, standardized pre-screen procedures. In 2016, the neuroscience center served over 300 research patient visits and 25,000 clinical visits from all islands and is growing at over 2500 NEW patients every year. The facility encompasses over 7,000 square feet of office space with 24 exam rooms dedicated to neuroscience including dedicated clinical trial facility and exam rooms.

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A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study of Crenezumab in Patients With Prodromal to Mild Alzheimer's Disease. (CREAD 2)

NIH Clinical Trial Info

- Evidence of the AD pathological process, by a positive amyloid assessment either on cerebrospinal fluid (CSF) amyloid beta 1-42 levels as measured on the Elecsys beta-amyloid (1-42) test system or amyloid positron emission tomography (PET) scan by qualitative read by the core/central PET laboratory
- Demonstrated abnormal memory function at early screening (up to 4 weeks before screening begins) or at screening
- Mild symptomatology, as defined by a screening MMSE score of >=22 points and CDR-GS of 0.5 or 1.0
- Meets National Institute on Aging/Alzheimer's Association (NIAAA) core clinical criteria for probable AD dementia or prodromal AD (consistent with the NIAAA diagnostic criteria and guidelines for mild cognitive impairment [MCI])
- If receiving symptomatic AD medications, the dosing regimen must have been stable for 3 months prior to screening

Sponsored by: Center for Healthy Aging, Memory & Brain Health, Hawaii Pacific Neuroscience

A Randomized, Double-Blind, Placebo-Controlled and Delayed-Start Study of LY3314814 in Mild Alzheimer's Dementia (DAYBREAK Study) Protocol I8D-MC-AZET

NIH Clinical Trial Info

- 55 to 85 years old
- Meet the National Institute on Aging (NIA) and the Alzheimer's Association (AA) (NIA-AA) criteria for probable AD dementia
- MMSE score of 20 to 26 inclusive

- CDR global score of 0.5 or 1, with the memory box score ≥0.5
- Willing to undergo Spinal Tap for evidence of amyloid/tau in CSF
- Have a reliable study partner

Sponsored by: Center for Healthy Aging, Memory & Brain Health, Hawaii Pacific Neuroscience

Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of ITI-007 in the Treatment of Agitation in Patients with Alzheimer's Dementia.

NIH Clinical Trial Info

55 years of age of older

• Has a clinical diagnosis of probable AD according to NIA-AA guidelines

• Has a MMSE score of 8 to 26 (inclusive) at screening;

• Has clinically significant symptom(s) of agitation secondary to probable AD, consistent with the International Psychogeriatric Association consensus definition

Sponsored by: Center for Healthy Aging, Memory & Brain Health, Hawaii Pacific Neuroscience

A Multicenter, Open-Label Study to Evaluate the Safety and Tolerability of Tozadenant as Adjunctive Therapy in Levodopa-Treated Patients with Parkinson Disease Experiencing End of Dose "Wearing-Off"

NIH Clinical Trial Info

Inclusion Criteria:

- Parkinson's disease diagnosis consistent with UK Parkinson's Disease Society Brain Bank Diagnostic criteria
- Minimum of 3 years since diagnosis.
- Good response to levodopa
- Patients must have been taking a levodopa-containing anti-PD medication continuously for at least the previous 12 months
- Patient has documented a minimum amount of Off time.

Sponsored by: Center for Parkinson's Disease, Movement Disorder & Neurodegenerative Disease

Sustained Effect of Droxidopa in Symptomatic Neurogenic Orthostatic Hypotension (RESTORE study)

NIH Clinical Trial Info

- 18 years or older and able to stand (with or without limited assistance)
- Clinical diagnosis of symptomatic orthostatic hypotension associated with Primary Autonomic Failure (PD, MSA or PAF) or NDAN or DBH Deficiency

- A documented drop of at least 20 mmHg in SBP, within 3 minutes of standing. This can either be documented in the patient history or assessed during Screening prior to the first Titration Visit
    - Sponsored by: Center for Parkinson's Disease, Movement Disorder & Neurodegenerative Disease

Open Label, Multicenter, Safety and Pharmacokinetics Study of YKP 3089 as Adjunctive Therapy in Partial Onset Seizures

NIH Clinical Trial Info

- Age 18-70
- > 30 kg
- Uncontrolled partial seizures and require additional AED therapy despite having been treated with at least one AED within approximately the last 2 years.
- Stable doses of 1 to 3 AEDs for at least 3 weeks prior to Visit 2
- Vagal nerve stimulator (VNS) will not be counted as an AED; however, the parameters must remain stable for at least 4 weeks prior to baseline. The VNS must have been implanted at least 5 months prior to Visit 1.
- Benzodiazepines taken at least once per week during the 1 month prior to Visit 1 for epilepsy, or for anxiety or sleep disorder, will be counted as 1 AED and must be continued unchanged throughout the study. Therefore only a maximum of 2 additional approved AEDs will be allowed.
- Computed tomography (CT) or magnetic resonance imaging (MRI) scan performed within the past 10 years that ruled out a progressive cause of epilepsy.

Sponsored by: Comprehensive Epilepsy Center, Hawaii Pacific Neuroscience

A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Trial of Pregabalin as Adjunctive Therapy in Pediatric and Adult Subjects with Primary Generalized Tonic-Clonic Seizures.

NIH Clinical Trial Info

- 5-65 years old
- Diagnosis of epilepsy with seizures classified as PGTC seizures according to the International League Against Epilepsy (ILAE 2010)
- Must have at least 1 PGTC seizure in the 8 weeks prior to screening.
- Must have a minimum of 3 PGTC seizures during the 8-week baseline phase and at least 1 PGTC in each 4-week period of the baseline phase.
- Currently receiving adequate and stable dosage of 1 to 3 anti-epileptic treatments (stable within 28 days of screening). Benzodiazepine medication used on a regular basis at a stable dosage will be considered 1 of the concurrent anti-epileptic treatments.

- A previously implanted vagus nerve stimulator (VNS) for the treatment of epilepsy is allowed and considered 1 of the 3 anti-epileptic treatments.

Sponsored by: Comprehensive Epilepsy Center, Hawaii Pacific Neuroscience

Randomized, Double-Blind, Double-Dummy, Parallel-Group Study Comparing the Efficacy and Safety of Ofatumumab versus Teriflunomide in Patients with Relapsing Remitting Multiple Sclerosis

NIH Clinical Trial info

Inclusion:

 18 to 55 Years (Inclusive)

 Diagnosis of MS according to the 2010 Revised McDonald criteria (Polman et al. 2011)

 Relapsing-remitting course (RRMS), or secondary progressive (SPMS) course with disease activity, as defined by Lublin et al 2014

 Disability status at Screening with an EDSS score of 0 to 5.5 (inclusive)

 Documentation of at least: 1 relapse during the previous 1 year

OR 2 relapses during the previous 2 years prior to Screening

OR a positive Gd-enhancing MRI scan during the year prior to randomization.

 Note: Screening MRI scan may be used if no positive Gd- enhancing scan exist from prior year.

 Neurologically stable within 1 month prior to randomization

Sponsored by: Clinical Research Center, Hawaii Pacific Neuroscience

With appreciation and Aloha for our patients & their families who

We learn so much from each and every day and for whom we get to humbly serve

Hawaii Pacific Neuroscience

Clinical & Research Faculty & Staff 2017