

Chronic Pain Clinical Trials at UC Davis

Contact Information

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Partnering goals

Phase I, II, III clinical trials for the following indications: addiction liability assessment, cannabinoid treatment of chronic pain, neuropathic pain treatments

UC Davis Division of Pain Management

Research Support:

- 7- Faculty
- 2 - Clinical Research Coordinators

Sacramento Area – Enrollment opportunities

The Greater Sacramento area houses over 1.8 million people. The area enjoys high ethnic diversity, and a variety of airway disease phenotypes. As of January 2008, the ethnic distribution in the area was as follows: 48% Whites (including the second largest Eastern European population in the US), 21.6% Hispanics, 15.5% Black, 16.6% Asian (among them more than 50% Laotian/Hmong, and Vietnamese), 0.9% Pacific Islanders, 1.3% American Indians. Foreign born population 20.3%, and 41.5% of them are naturalized citizens.

Recent Chronic Pain Clinical Trials Performed at UC Davis

Clinical Trial	Indication	Trial Type	Enrollment	Status
CTSC Clinical Research Center A Randomized, Placebo Controlled Cross-Over Trial of Cannabis Cigarettes in Neuropathic Pain	Neuropathic pain	Phase III	39 subjects	Enrollment completed

Wilsey B, Marcotte T, Tsodikov A, Millman J, Fishman S Journal of Pain (in press)				
CTSC Clinical Research Center The Analgesic Effect Of Vaporized Cannabis On Neuropathic Pain University of California Center for Medicinal Cannabinoid Research 2007-9	Spinal Cord Injury Pain	Phase III	Starting fall 2008	Not yet enrolling
CTSC Clinical Research Center A Comparison of the Addiction Liability of Hydrocodone and Sustained-Release Morphine UC Davis Health Systems Research Award Program 2005-7	Chronic pain	Phase III	12 subjects completed	Enrollment completed

Additional Facilities for Phase 0 and Phase I Studies

The CTSC Clinical Research Center is a dedicated clinical research facility accessible by any UCDMC staff physician for Phase 0 and Phase I clinical trials. These facilities are governed by the National Center for Research Resources (NCRR), a center of the National Institutes of Health (NIH) under the Clinical and Translational Science Award program.

The UC Davis CCRC is a collaboration between the University and the Veterans Affairs Northern California Healthcare System (VANCHCS). The CCRC is located in an 8,000-square-foot area on the fourth floor in the new inpatient tower at the Sacramento VA Medical Center at Mather, about 10 miles east of the UC Davis Medical Center in Sacramento.

The nine-bed facility consists of three double and three single-patient rooms, a designated metabolic kitchen, a core laboratory, a body composition unit, videotaping facilities and offices for biostatistics, informatics and the administrative staff. In addition, the center has all the resources required for an inpatient facility, including a communication center, utility rooms, diagnostic area, storage facility and patient day room. Adjacent to the CCRC is a state-of-the-art imaging facility including PET, MRI and standard radiology equipment available to CCRC users.

The CCRC is staffed with thirteen highly skilled RNs provide 24/7 care to subjects enrolled in clinical research studies at CCRC and on the main campus. RNs are specially trained in Human Subjects Protection, Good Clinical Practices, and Research Protocol Adherence; all are Chemotherapy, Conscious Sedation, and ACLS certified. Exercise Physiologist has a variety of methods of measuring body composition, bone density, metabolic rate and exercise fit. The CCRC houses a BOD POD, DEXA machine, Metabolic Cart, 12 Lead EKG Stree Treadmill system and much more. Research Dietitian provides nutritional support to study protocols by providing nutritional analysis, designing specialized meal plans, providing nutritional counseling to subjects, and on-site food preparation

CTSC Clinical Research Center Laboratory

The Laboratory Core manages the collection, flow and disposition of biological specimens collected for CCRC studies.

Specimen Processing

-SOP's for specimen processing are written to ensure that all specimens (single or multiple blood, serum, plasma or urine) are collected and processed in accordance with the approved instructions specific for each protocol

Clinical Analysis

UCDHS Clinical Pathology Services is a primary laboratory for routine analysis for the CCRC. The VAMC Clinical Lab will assist the GCRC in situations that require STAT lab results.

Specimen Storage

The Core Laboratory has a 4°C refrigerator, one upright -20°C and three -80°C freezers for short term specimen storage, monitored daily for temperature control.

Specialized Analyses:

The laboratory personnel can help with isolation of cells from peripheral blood, flow cytometry as well as isolation of DNA/RNA and other esoteric testing as necessary for the different protocols.

Multiplexing on the Bioplex and BD FACS Array:

2 different platforms are available for multiplexing and in combination provide a variety of tests that can be multiplexed according to the needs of a particular protocol