

Asthma and COPD Clinical Trials at UC Davis

Contact Information

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Partnering goals

Phase I, II, III clinical trials for the following indications: asthma, COPD, emphysema, interventional bronchoscopy in airways diseases

UC Davis Division of Pulmonary and Critical Care Medicine

Research Support:

- 15- Faculty
 - 6 - Clinical Research Coordinators (3 SOCRA certified CCRP's, 3 not yet certified)
 - 2- Registered Respiratory Therapists
 - 1- Research Registered Nurse – assists with inpatient trial procedures (ie, ECGs, blood draws, medication administration, etc.)

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. The following table shows the number of unique patients seen during the period of 5/2007-5/2008.

ICD CLASS	DX CLASS	#PATIENTS SEEN
490	BRONCHITIS	1147
491	CHRONIC BRONCHITIS	493
492	EMPHYSEMA	533
493	ASTHMA	11467
494	BRONCHIECTISIS	212
495	EXTRINSICALLERGIC ALVEOLITIS	30
496	CHRONIC AIRWAY OBSTRUCTION NEC	1488

Recent Asthma and COPD Clinical Trials Performed at UC Davis, Pulmonary/Critical Care Division

Clinical Trial	Indication	Trial Type	Enrollment	Status
A Phase IIIb Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Xolair in Subjects with Moderate to Severe Persistent Asthma Who are Inadequately Controlled with High-Dose Inhaled Corticosteroids and Long-Acting Beta-Agonists (Genentech) (PI: S. Louie, Co-PI: N. Kenyon)	Severe Asthma	Phase IIIb drug trial	Recently opened at our site (4 subjects to date)	Currently enrolling
Fish oil in severe asthma patients with ALOX5 polymorphisms (Center for Health and Nutrition Research) (PI: N. Kenyon)	Severe asthma	Pilot	Ongoing (12 subjects to date)	Currently enrolling
Detection of Novel Biomarkers of Asthma and COPD in Exhaled Breath (NIH/NCRR) (PI: C. Davis, Co-PI: N. Kenyon)	Severe asthma, COPD	Pilot	Ongoing (25 subjects to date)	Currently enrolling
EASE study - A Randomized, Double-Blind Study To Evaluate The Safety and Effectiveness of the Exhale Drug-Eluting Stent In Homogeneous Emphysema subjects With Severe Hyperinflation (Broncus Tech.) (PI: A. Chan, Co-PI: R. Allen)	Bronchoscopy emphysema / COPD palliation	Pivotal device trial	Ongoing (40+ subjects consented to date)	Currently enrolling
IBV Trial - A Prospective, Randomized, Controlled Multi-Center Clinical Trial to Evaluate the Safety and Effectiveness of the IBV® Valve System for the Treatment of Severe Emphysema (Spiration Inc.) (PI: A. Chan, Co-PI: R. Allen)	Bronchoscopy emphysema / COPD palliation	Pivotal device trial	Ongoing (20+ subjects consented to date)	Currently enrolling
LAS-MD-CL26 study - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 6 Week Clinical Study to Assess the Effect of Inhaled Acclidinium Bromide (LAS34273) 200 mcg on Exercise Endurance and Lung Hyperinflation in Patients with Moderate to Severe Chronic Obstructive Pulmonary Disease (COPD) (Forest Research Institute) (PI: A. Chan, Co-PI: R. Allen)	Emphysema / COPD palliation	Phase III drug trial	Ongoing, started Mar/08	Currently enrolling
VENT study - Endobronchial Valve for Emphysema Palliation Trial (Emphasys Medical Inc.) (PI: A. Chan, Co-PI: R. Allen)	Bronchoscopy emphysema / COPD palliation	Pivotal device trial	24 subjects randomized (top 5 in US)	Recruitment goal met, now closed to enrollment.
TENOR Study - An Observational Study of the Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens (Genentech) (PI: S. Louie)	Severe asthma	Observational	17 subjects	Now closed.

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