

Orthopaedic Clinical trials at UC Davis

Contact Information

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Partnering goals

Phase I, II, III clinical trials for the following indications: osteoarthritis, joint pain, osteoporosis, dysplasia, treatment of fractures, and bone necrosis.

Clinical Trial experience

2007-2008: A Randomized, Double-Blind, Active-and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of CG5503 Immediate-Release (IR) Formulation in the Treatment of Acute Pain from Total Hip Replacement followed by a Voluntary Open-Label Extension

Sponsor = Johnson & Johnson Pharmaceuticals

Enrolled 10 patients within 6 months of site initiation visit (May 2007-Nov 2007). We were one of the five top sites for patient enrollment amongst U.S. sites.

2005-current ReCap Total Resurfacing System Clinical Study
Sponsor = Biomet
Enrolled 5 patients within 5 months of site initiation visit (Feb 2006-July 2006). Enrollment on hold until Biomet alignment device approved by the FDA.

UC Davis Department of Orthopaedics

Research Support:

- 18- Faculty Orthopaedic Surgeons
- 1- Clinical Research Coordinator (SOCRA certified)
- 1- Physician Assistant – assists with clinical research procedures (ie, physical exams).

- 1- Research Registered Nurse – assists with inpatient trial procedures (ie, ECGs, blood draws, medication administration, etc.)

Clinical Trials Performed at UC Davis Orthopaedic Surgery Dept.

Clinical Trial	Indication	Trial Type	Enrollment	Status
Johnson& Johnson: Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of CG5503 Immediate-Release	Pain Following Total Hip Arthroplasty	Multicenter	10	Completed
Biomet: ReCap Total Resurfacing System	Hip Arthritis	Multicenter	5	Ongoing- on hold until FDA approval of accessory surgical tool used for device alignment

Sacramento Area – Enrollment opportunities

The Greater Sacramento area houses over 1.8 million people. The area enjoys high ethnic diversity, reflected in the population of the Orthopaedic Department. 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% America Indians. Foreign born population 20.3%, and 41.5% of them are naturalized citizens.

	Osteoarthritis	Joint Pain	Ankle Fractures	Carpal Tunnel	Hip/Knee Joint Replacement
Approx. Number of Patients treated in the past year	440	440	120	130	200

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. The patient rooms are flexibly designed to allow for inpatient and outpatient activities. 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 designated as the 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 access to a 4°C refrigerator, one upright -20°C and three -80°C freezers for short term specimen storage. All refrigerators and freezers are monitored daily for efficient and accurate 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