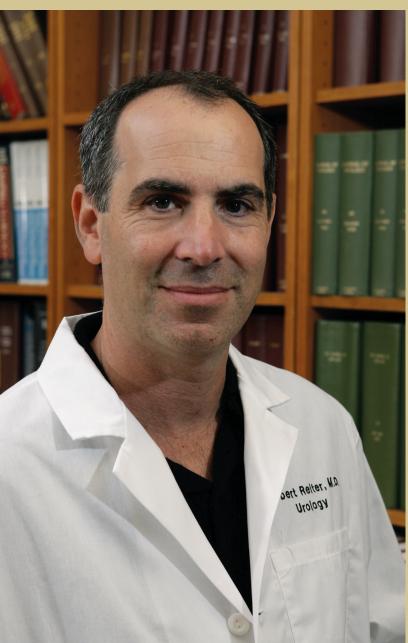
# CLA Grandical Center

## UCLA Prostate Cancer Program: Offering the Best of Today's Treatments,

Researching Tomorrow's Solutions



From Radiation to Robotics, Tailoring Treatment to the Individual Is Key First of Two Parts

rostate cancer is the second-leading cause of cancer death in men. It is a cancer that, when diagnosed and treated early, is highly curable - and one for which there are many different treatment options, each with its own pros and cons when it comes to efficacy and quality of life impact. The risk of early-stage prostate tumors is wide ranging - some are fast-growing and require aggressive measures, others are slow-growing and pose minimal threat adding to the importance of a thorough and accurate diagnosis.

Given the individual nature of the treatment decision, a comprehensive program has many advantages. "Our belief is that there is no one therapy that is right for everyone, and that it is very important to tailor treatment to the patient's tumor, age, expectations, personality and lifestyle," says Robert Reiter, MD, professor of urology and director of the UCLA Prostate Cancer Program.

Few centers are as comprehensive as the UCLA Prostate Cancer Program, which not only offers the full spectrum of treatment options, but also integrates research with clinical care. The program monitors the results of each approach in an effort to provide better clarity for future decisions; conducts research leading to new therapies and better diagnostic methods; and makes experimental treatments available to high-risk patients through clinical trials.

In this, the first of a two-part series on the UCLA Prostate Cancer Program, we discuss the new and conventional treatment options offered at UCLA for men with early-stage prostate cancer. In the next issue, we will discuss how research is improving the diagnosis and treatment of early-stage prostate cancer, offering new hope for patients with advanced prostate cancer, and identifying exciting new strategies for preventing prostate cancer and its recurrence. continued on page 4

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#### Do You Want to Help?

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Please feel free to call 310-825-5056

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David Geffen School of Medicine at UCLA

Department of Urology

## Integrative Urology Program



From left: Allan Pantuck, MD; Mark Ryan, licensed acupuncturist and herbal medicine specialist; and Christopher Saigal, MD, MPH

s men age, many develop urologic conditions that can affect their quality of life. Among men in their 50s, one in four suffers from erectile dysfunction, and one in four experiences moderate to severe urinary problems. One in five men 60 and older suffers from the effects of an abnormally low testosterone level. One in six men is diagnosed with prostate cancer in his lifetime.

Many assume that there is nothing they can do to prevent these problems. "There is a mindset that this is just part of aging, but that's not necessarily the case," says Christopher Saigal, MD, MPH, assistant professor of urology at UCLA. "They are more common as we get older, but the choices we make can go a long way toward reducing the likelihood that they will occur."

The new UCLA Integrative Urology Program aims to help men reduce risk and manage care for these common urologic afflictions. Designed for men over the age of 35, it is one of only a handful of programs in the country specifically addressing men's health needs, according to Dr Saigal, the program's director. The program's unique approach offers patients a medical examination and consultation with a urologist, a nutrition strategy with a dietician, and a consultation with a doctor of traditional Chinese medicine on acupuncture and herbal supplements. Together, these specialists work with each man to map

out the best strategy, whether it's addressing concerns about a family history of disease, treatment for a urological condition, or simply planning a healthier lifestyle to increase the chances of preventing disease.

"As urologists, many of us take care of problems after they have reached the point where they are very challenging to treat, and we often wish we could have intervened earlier," says Dr Saigal. "In addition, our patients often ask us about herbal and alternative therapies and nutritional strategies that they have heard about, and there's so much information out there and confusion about what is proven and what is not. So we decided to develop a program offering reliable, accurate information about complementary therapies and solid nutritional advice, delivered synergistically with Western medical counseling."

The program offers integrative approaches based on the latest research, such as data recently published by Dr Allan Pantuck, associate professor of urology and a physician with the program, on the effects of pomegranate juice on prostate cancer. Dr Saigal has studied the impact of obesity on men's urologic health, and the program helps patients take steps toward maintaining a healthy weight. Patients are also advised how to best incorporate yoga and other moderate exercise into their lives.

"It's important to engage men in thinking about prevention, because too often they are inclined to wait until something is 'broken' to fix it," says Dr Saigal.



Jennifer Singer, MD, Kidney Transplant Surgeon, Pediatric Urology

#### Proper Care of Children with Chronic Kidney Failure Vital to Transplant Success

ost children who suffer kidney failure as a result of underlying urological problems are able to benefit from transplantation, despite the complications that are often presented by the underlying cause of the kidney failure, according to Jennifer S. Singer, MD, assistant professor of pediatric urology and transplantation at UCLA. Statistics from the U.S. Renal Data System indicate that transplantation confers significant survival benefits for these children over dialysis. But, Dr Singer said, proper evaluation and management are important in preparing them for the transplant, and in some cases, urologic reconstruction is necessary.

In "Urologic Reconstruction in Children with Chronic Renal Failure or Transplantation," a State-of-the-Art Lecture given at the American Urological Association annual meeting earlier this year, Dr Singer noted that most of the approximately 1,200 children who are diagnosed with chronic kidney disease in the United States each year eventually require and receive kidney transplants. She added that these children should be carefully assessed for any abnormalities

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Shlomo Raz, MD, and Larissa Rodríguez, MD, are pleased to announce the accreditation of the UCLA Fellowship in Female Urology,

are pleased to announce the accreditation of the UCLA Fellowship in Female Urology, Reconstructive Surgery, and Urodynamics by the American College of Obstetricians and Gynecologists and the Board of Urology Joint Fellowship. In July 2006 the first two-year fellows started the program. They will each be spending a full 12 months in research as well as a year of clinical practice under Drs Raz and Rodríguez.

Christian Twiss, MD, clinical fellow, is a recipient of The American Urogynecologic Society (AUGS) Foundation's Research Award, a one-year grant for his research project entitled "Association of LAMC-1 as a Predictor of Pelvic Organ Prolapse." The field of urogynecology (a subspecialty within Obstetrics and Gynecology) is dedicated to the treatment of women with pelvic floor disorders such as urinary or fecal incontinence and prolapse (bulging or falling) of the vagina, bladder and/or uterus. The AUGS Foundation's research awards aim to develop leaders who will be responsible for making medical advances in urogynecology that will ultimately improve the quality of health care of all women. Dr Twiss is the first urologist to receive the award.

John Gore, MD, one of UCLA's three chief residents, was awarded a prestigious and highly competitive honor in being named a Robert Wood Johnson Clinical Scholar. This fellowship will begin in July 2007. Physicians in the Robert Wood Johnson Clinical Scholars Program complete two years of graduate-level study as part of an academic training program, with all their time devoted to research. After completing this fellowship, Dr Gore will be one of only a handful of urologists in the world with fellowship training in health services research.

Valerie Arboleda, medical student, was awarded a research grant from the American Federation of Aging to conduct research on the impact of aging on adipose stem cells (ASCs). ASCs possess multi-lineage potential and have been shown to differentiate into a number of tissues, including bone, smooth muscle, and fat. ASCs are believed to have the potential to provide cures for many degenerative diseases.

Marxa Leao Figueiredo, PhD, postgraduate researcher in the laboratory of Lily Wu, MD, PhD, was awarded a \$113,400 Career Development Award from the National Cancer Institute for a project titled "p12cdk2ap1 Regulation of Normal and Neoplastic Growth."

Joanne Leung, BS, a PhD student, was granted a one-year predoctoral fellowship from the California Institute of Regenerative Medicine on behalf of the UCLA Institute for Stem Cell Biology and Medicine. Ms Leung's research project will explore the role of extracellular matrix and growth factors on an elastomeric scaffold to induce smooth muscle differentiation of adipose (fat, or tissue containing fat cells) stem cells for tissue engineering of the urinary bladder.

Sally L. Maliski, PhD, assistant professor in the UCLA School of Nursing, recently received a Prostate Cancer Health Disparity Research Award from the Department of Defense for a three-year study entitled, "The Impact of Prostate Cancer Treatment-Related Symptoms on Low Income Latina Couples." Dr Maliski has collaborated closely with Mark S. Litwin, MD, MPH, professor of urology and health services, on UCLA's statewide IMPACT program that treats low-income and uninsured Californians with prostate cancer.



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#### **Robotic Procedure Offers Benefits**

For many men with early-stage prostate cancer, the robotically assisted minimally invasive prostatectomy has emerged as an attractive option. Dr Reiter, who has performed more than 100 of these procedures since UCLA began using the robots more than two years ago, is achieving results that are equivalent to the traditional open surgical approach to nerve-sparing radical prostatectomy. Along with Dr Reiter, the procedure is being offered at UCLA by Peter G. Schulam, MD, PhD, associate professor of urology.

"The ability to achieve results that are comparable to open surgery when it comes to eliminating cancer and preserving sexual potency and urinary continence makes the robotic approach attractive to many early-stage prostate cancer patients," says Dr Reiter, "since it offers the advantages of shorter hospital stay and recovery time and less blood loss, pain and scarring."

Minimally invasive (laparoscopic) prostatectomy

capitalizes on the latest fiber optics

Above left: Dr Peter Schulam performing a robotically assisted laparoscopic prostatectomy using the da Vinci robotic surgical system. Above right: Surgical view on monitor

technology to enable surgeons to poke needle-sized holes into patients, obtain pictures of the surgical site with 15-fold magnification, and insert miniaturized instruments to remove the prostate. The introduction of robotic instruments has helped to improve surgical precision. Surgeons are able to sit in a console with a three-dimensional view inside the patient

> and move three robotic arms with the full natural range of motion, while a fourth robotic arm controls the camera. The

instruments can act like human wrists, giving surgeons greater flexibility as they use the robot to manipulate the tiny surgical tools inside the body.

Studies of outcomes with the robotically assisted minimally invasive prostatectomies at UCLA have been very encouraging. Arguably the most important indicator of the success of a nerve-sparing radical prostatectomy is whether there are positive surgical margins - cancer found at the farthest edges of the specimen after it is removed. When this occurs - as it does as often as 40% of the time in the community - the risk of recurrence is twice as high as when it does not. Of more than 100 robotically assisted minimally invasive prostatectomies at UCLA, the positive margin rate is only 10% - equal to the rate of the open approach, and as low as any rates reported in the nation. In addition, less than 2% of the UCLA robotic surgeries have resulted in the need for a blood transfusion, a major advantage over

open prostatectomy.

Data on potency and continence outcomes with robotic prostatectomy are still being "It is very collected, important to

tumor, age,

personality,

- Dr Robert

Reiter

but appear to be excellent, according to Dr tailor treatment prostate under ultrasound Reiter. Based on early results, he to the patient's and his colleagues modified the surgery to include a procedure expectations, in which the bladder and urethra leading to the pubic bone are and lifestyle." suspended during the operation, better enabling the surgeon to return the patient's anatomy to its natural state. This so-called bladder-neck suspension helps patients regain urinary control sooner.

#### New Strategies for "Open" Surgeries

For some patients, the nerve-sparing radical prostatectomy continues to be the best option. In the hands of experienced surgeons, this "open" operation is highly effective in removing the cancer and preserving potency. Dr Reiter and Dr Jean deKernion, professor and chair of the Department of Urology, now have a database that includes the results of more than 1,400 patients treated with the surgery by the UCLA faculty (in addition to Drs Reiter and deKernion, Drs Arie Belldegrun, Mark Litwin, Jacob Rajfer and Robert B.

Smith also offer the surgery); it indicates that 80%-90% of patients under the age of 60 regain their sexual function, with a 5%-10% risk of stress urinary incontinence after one year. Recovery time for the procedure is quicker than in the past - hospitalization has been reduced to two days, with catheterization averaging seven days and patients returning to regular activities in as little as 2-4 weeks.

Dr Reiter and colleagues have adopted new strategies in an effort to improve nerve-sparing abilities for surgical patients. During the open procedure, patients with bulkier tumors and aggressive cancers are monitored pathologically by the surgeons, who obtain frozen sections when necessary to better facilitate decisions on preserving the nerves. Medications such as Viagra are being given to prostate cancer patients both pre- and postoperatively to enhance potency rehabilitation.

#### **Non-Surgical Options**

Several non-surgical options are also available for early-stage prostate cancer patients. Since the early 1990s, UCLA has offered brachytherapy, in which a urologist, working in collaboration with a radiation

oncologist and physicist, implants small radioactive pellets, or seeds, into the guidance. The pellets then emit high doses of radiation exclusively to the prostate over the course of several months, minimizing radiation exposure to the surrounding healthy tissues. At UCLA, which has an extensive database of brachytherapy cases, patients

return for follow-up visits a month after the procedure so that their doctors can ensure through a CT scan that the radiation is being appropriately distributed.

"This is a very good treatment for patients with low-risk tumors," says Dr Reiter. "It's a one-hour outpatient procedure with minimal pain and no prolonged catheterization. The side effects are extremely low – some urinary frequency or slow urination issues that can be treated medically, and a risk of impotence in older men that appears to be lower than the risk from surgery. Most patients can return to their regular activities within a few days."

UCLA is also bringing the latest advances in radiotherapy to patients who opt for radiation treatment over surgery.

With advances in computer and imaging technology, radiation treatment has evolved in recent years. "The idea is to get higher doses of radiation specifically aimed at the prostate gland while avoiding or minimizing toxicity to the surrounding tissue - the bladder and rectum," says Steve P. Lee, MD, PhD, associate professor and interim chair of the Department of Radiation Oncology. During the course of radiation treatment, which typically lasts 6-8 weeks, the tumor and prostate gland can move. So Dr Lee and his urology colleagues have begun using the newest technique, image-guided radiotherapy (IGRT). Three seeds are implanted inside the prostate to provide a way of tracking the gland; this allows Dr Lee's team, with the aid of the computerguided technology, to adjust the radiation beam based on a more up-to-date view of the position of the target tumor and organs. IGRT is currently being offered to patients with low-risk early-stage prostate cancers.

When patients experience a cancer recurrence following radiation treatment, surgery tends not to be a good option. For these individuals, cryotherapy can be an effective alternative. Cryotherapy involves the application of extreme cold to destroy diseased tissue, including cancer cells. At UCLA, Dr Arie Belldegrun, professor of urology, has been offering the latest in cryotherapy using smaller and smaller needles for better access to the prostate gland. In addition to patients who have previously had radiation treatment, men who are not concerned about potency may find cryotherapy appealing: Aside from impotence, which occurs in all patients, the procedure's side-effect profile is favorable compared to other prostate cancer treatments.

#### Tailored Treatments for Low-, High-Risk Tumors

Increasingly, treatments are becoming more tailored to the risk posed by the patient's cancer, Dr Reiter notes. For the roughly 5% of patients undergoing prostate cancer surgery who have tumors that are considered to be at high risk of spreading to the lymph nodes, UCLA urologists have begun performing extended lymph node dissections, in which they remove the lymph nodes from the pelvis. For patients who require this approach, the open surgical technique is typically used.

At the other end of the spectrum are patients with low-risk cancers that might necessitate minimal or no therapy. The latest approach for this group involves focal treatments: Rather than removing or irradiating the entire prostate, the surgeon pinpoints the portion where the cancer is located and treats only that area in an effort to minimize, or even eliminate, the side effects that typically accompany surgery and radiation. UCLA is now one of two centers in the nation to begin an experimental protocol for one such treatment, a photoablation therapy known as Tookad. After a needle is injected into the lesion area, rays of light are aimed at the tumor region in an effort to kill the cancer cells.

"This is where the future is going

– toward more aggressive treatments for
patients who really need them, and less
aggressive treatments for patients who may
or may not need anything," says Dr Reiter.

#### Advantages of a Comprehensive Program

Survival is the number-one goal for patients and their doctors after a diagnosis of early-stage prostate cancer. But often, it isn't clear which treatment strategy is superior, and patients find themselves facing difficult choices among therapies that have varying potential side effects - effects that, given the high success rates of localized prostate cancer treatment and the slow-growing nature of most prostate tumors, they are likely to live with for many years. Nationally, few studies have been done on the quality of life effects of each treatment. That's why the UCLA Prostate Cancer Program's large database tracking survival and quality of life outcomes - the latter as determined by patient questionnaires – is such a valuable tool.

In choosing among the urological treatments, patients should consider that the most important factors in predicting prostate surgery outcomes are the surgeon's experience and skill. UCLA is among the nation's most active centers for prostate cancer treatment, an important fact given a recent study indicating that high surgeon volume correlates with lower in-hospital complications and length of stay for men undergoing radical prostatectomy. Says Dr Reiter: "Patients need to ask about treatment options, quality of life outcomes, and surgical track records. We are proud of the UCLA Prostate Cancer Program's comprehensive nature, large database, and outcomes that are as good as any in the country."



From left: Richard C. Carolan, Tina Carolan and Richard V. Carolan

### Richard and Tina Carolan: First with Support for UCLA Prostate Cancer Program

he UCLA Department of Urology is proud to recognize the generous support of Tina and Richard Carolan. In 1992, their giving established the first prostate cancer research fund at UCLA, which supported the initial investigations that eventually resulted in new and improved prostate treatments and better diagnostic tools. The Carolans' support also set the standard for other donors, who have created their own prostate cancer research funds to benefit the Department.

The Carolans divided their time between homes in New Jersey and Southern California. After Mr Carolan's prostate cancer operation in New York, they wanted to establish a connection with a leading urologist on the West Coast. On the recommendation of their East Coast cancer center, they chose Dr Jean B. deKernion, chair of UCLA's then-Division of Urology.

The Carolans found Dr deKernion to be a very caring and compassionate physician. They were also impressed by his passionate involvement in searching for a cure for prostate cancer. They saw that

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CAROLANS from page 5 Dr deKernion was working diligently to recruit the right people to UCLA in order to build a world-class team of physicians and scientists, who would expand the search and make UCLA a leader in the field. The Carolans became a part of this discovery and growth through their friendship, involvement, and support of the university's cancer research programs.

Since the couple's early giving, the Department of Urology's prostate cancer research program has become a nationally acclaimed center of excellence as designated by the National Cancer Institute, which named it a Specialized Program of Research Excellence in 2002. Additionally, recognizing UCLA as a leader in prostate cancer treatment, the State of California awarded UCLA \$50 million in 2001 to administer IMPACT, a statewide program targeting uninsured men.

Following Mr Carolan's death from prostate cancer in 2002, Mrs Carolan has maintained her partnership with Dr deKernion and the Department of Urology. She is aware of the high rate of occurrence of prostate cancer and wants KIDNEY FAILURE from page 3

in the bladder area, which serves as the conduit through which the transplanted kidney will drain.

All of these children should undergo upper urinary tract evaluation, Dr Singer said, and some, depending on their history and symptoms, should also be given lower tract evaluations. "Early intervention and appropriately timed reconstruction are crucial components to a successful outcome after transplantation," Dr Singer said.

She explained that early intervention includes identifying and properly managing children at risk for upper urinary tract deterioration, including those who require frequent catheterization. In addition, children with chronic kidney disease should be monitored with annual ultrasound screening, preventive antibiotics, and drug therapy as necessary. Close attention should be paid to any structural problems leading to urinary reflux, and urodynamic studies should be conducted to determine if and when bladder augmentation should be performed, Dr Singer added.

### Kidney Cancer Program **Announces New Medical Director**



Fairooz Kabbinavar, MD

ince its founding in 1990 by Arie Belldegrun, MD, and Robert Figlin, MD, the UCLA Kidney Cancer Program has become a model comprehensive research and patient care program, attracting physicians, scientists, and other practitioners who come from all over the world to train and study with the team. On September 1, 2006, the program said farewell to Dr Figlin, who is pursuing other opportunities. All involved with the program are grateful to Dr Figlin for his many years of dedication and wish him well.

The program is also pleased to announce the appointment of Fairooz F. Kabbinavar, MD, as the new medical director. Dr Kabbinavar is an associate professor in

the Division of Hematology/Oncology and a leading member of the Jonsson Comprehensive Cancer Center. He completed his internship and residency training at Harvard Medical School in Boston, followed by a medical hematology/ oncology fellowship at UCLA. He has

Dr Kabbinavar's extensive expertise in the Division in urologic oncology clinical research includes kidney cancer, prostate cancer and other genitourinary malignancies.

been a full-time faculty member of Hematology/ Oncology at UCLA since 1994. Dr Kabbinavar's extensive expertise in urologic oncology clinical research includes kidney cancer, prostate cancer and

other genitourinary malignancies. A great strength that he brings to the program is his experience in pioneering new approaches of targeted therapies for cancer with special focus on anti-angiogenic drugs both in the laboratory and the clinics. Dr Kabbinavar joins the Kidney Cancer Program team at a time when the program is expanding the scope of, and access to, the newest pharmaceutical therapies and medical devices that are currently being developed for the benefit of patients with all stages of kidney cancer. For more information on Dr Kabbinavar or the Kidney Cancer Program, please call Nazy Zomorodian, MSN, CUNP, at (310) 794-7704.

## Coming and Goings in the Department

he close of the academic year in June marked the end of urology residencies for three physicians and the start of two new urology careers. The three outgoing residents were honored at the June 9 graduation, where Mark Soloway, MD, the chairman of the Department of Urology and professor and chief of service at University of Miami School of Medicine, gave the evening's keynote address on the topic of "Practical Issues in Bladder Cancer: Putting Guidelines into Practice."

#### **Graduating Residents**

- -Dr Andrew Chen, the recipient of the Willard E. Goodwin Resident Teaching Award, will be moving to New York to complete a one-year endourology fellowship at St. Vincent's Medical Center.
- -Dr Jonathan Chin is entering private practice in northern California.
- -Dr Oleg Shvarts will be joining the group at Kaiser Permanente, Sunset.

#### **Incoming Residents**

- -Dr Jeffrey Bassett is joining the Department after completing medical school at University of Pittsburgh School of Medicine.
- -Dr Timothy Daskivich joins the residency program from Harvard Medical School.



#### **Graduating Fellows**

- -Dr Jennifer Anger, who completed a two-year fellowship with Dr Mark Litwin in urological health services research, will be continuing her academic career in the UCLA Department of Urology, having accepted an appointment as assistant professor within the Division of Female Urology and Reconstruction.
- -Dr Joseph Liao, who completed a two-year pediatric fellowship with Dr Bernard Churchill and a one-year endourology fellowship with Dr Peter Schulam, joined
- the faculty at Stanford School of Medicine, as assistant professor and chief of urology at the VA Palo Alto Health Care System and codirector of the Section of Laparoscopic and Minimally Invasive Urologic Surgery.

-Dr Arthur Mourtzinos, who completed a one-year fellowship in urodynamics and female urology with Drs Shlomo Raz and Larissa Rodríguez, joined the urology faculty at the Lahey Clinic in Burlington, MA.

#### Incoming and Continuing Postdoctoral Fellows

- -Dr John Lam, after completion of his three-year urologic oncology fellowship with Drs Arie Belldegrun, Jean deKernion and Robert Reiter, will begin a one-year endourology fellowship with Dr Peter Schulam.
- -Dr David Miller will be completing a one-year fellowship in urological health services research with Dr Mark Litwin, and then a one-year urologic oncology fellowship with Drs Arie Belldegrun, Jean deKernion and Robert Reiter. Dr Miller joins the Department from the University of Michigan Medical Center.
- -Dr Stephen Riggs, who completed his residency training at University of Mississippi Medical Center, will begin a two-year urologic oncology fellowship with Drs Arie Belldegrun, Jean deKernion and Robert Reiter.
- -Dr Jeffrey Veale continues his two-year transplantation fellowship with Dr H. Albin Gritsch.
- -Dr Veronica Triaca joins the Department as a fellow in the area of female urology and urodynamics with Drs Shlomo Raz and Larissa Rodríguez. Dr Triaca completed her residency training at Lahey Clinic Medical Center in Burlington, MA.
- -Dr Christian Twiss, who completed his residency at the New York University Medical Center, will begin a two-year fellowship in the area of female urology and urodynamics with Drs Shlomo Raz and Larissa Rodríguez.













# Clinical Trials in Urology Discovering New Ways to Care he UCLA Department of KIDNEY CANCER

he UCLA Department of Urology is committed to ongoing research in a quest to develop new treatments and cures for all urologic conditions. Our team has been instrumental in making major breakthroughs in the areas of

- Prostate cancer, prostatitis, and BPH (benign prostate hyperplasia) treatments
- Kidney cancer and transplantation
- Male infertility and sexual dysfunction
- Pelvic medicine, incontinence and reconstructive surgery

What sets the UCLA Department of Urology apart from others nationwide is the close collaboration and partnership of research scientists with faculty members — internationally renowned physician specialists in their fields — on advancing the field of urology. Many of these relationships also include involvement with researchers and physicians in UCLA's Jonsson Comprehensive Cancer Center. This unique collaboration makes UCLA a leader in new treatments and cures for urology patients nationwide.

Do you want to find out if you're eligible to participate in a UCLA Urology Clinical Trial? Most of the trials listed below are open and accepting applicants. Call Nazy Zomorodian, MSN, CUNP, at (310) 794-7704 or go to www.uclaurology.com and click on the "Research & Clinical Trials" link for more information.

#### **BLADDER CANCER AND DISORDERS**

- Bladder Cancer, Principal Investigator (PI): Arie Belldegrun, MD – A phase II clinical trial of green tea extract and Tarceva to prevent clinical bladder cancer recurrence in former smokers at high risk
- Female Urology Interstitial Cystitis, PI: Larissa Rodríguez, MD – A study to evaluate the effectiveness of acupuncture on symptoms of interstitial cystitis
- Uropathogen Detection, PI: Bernard M. Churchill, MD – Using DNA biosensors, this study investigates a detection system that would identify uropathogens quickly and enable point-of-care diagnosis and treatment of urinary tract infections.

#### **KIDNEY CANCER**

- Kidney Cancer, PI: Fairooz Kabbinavar, MD - A phase II study of M200 (anti-a 5ß1 integrin monoclonal antibody) in patients with metastatic renal cell carcinoma (VEGF)
- Kidney Cancer, PI: Fairooz Kabbinavar, MD - A phase III, randomized study to determine the efficacy and safety of single-agent SU011248 compared to IFN as a first-line therapy in patients with metastatic RCC. As with the above, this is for patients with kidney cancer that has spread to other parts of the body.
- Kidney Cancer Adjuvant Trial, Non-Metastatic Disease, PI: Arie Belldegrun, MD – The purpose of this trial is to evaluate the efficacy and safety of adjuvant cG250 treatment versus placebo in patients post-nephrectomy (no more than six weeks) with surgically completely resected clear cell renal cell carcinoma at high risk of recurrence. This trial is for patients who have been cured of kidney cancer by surgery but have a risk of developing tumor recurrence in the future.
- Kidney Cancer Metastatic RCC, Previously Untreated, PI: Fairooz Kabbinavar, MD – A phase II study of recombinant human lactoferrin in patients with advanced RCC who have failed at least one regimen of systemic treatment. Patients who have advanced kidney cancer and have not responded to an initial drug treatment may qualify for this treatment.
- Kidney Cancer PI: Dr Fairooz Kabbinavar, MD – A phase II study of GW786034 in subjects with locally recurrent or metastatic clear-cell renal cell carcinoma (Glaxo Smith Kline)
- Kidney Cancer PI: Fairooz Kabbinavar, MD - A randomized phase III study of the efficacy and safety of Sunitinib Malate alone or in combination with Interferon Alfa-2b as first line therapy for metastatic renal cell cancer (Renal **EFFECT Trial**)

#### KIDNEY TRANSPLANTATION

• Kidney Transplantation, Co-PI: H. Albin Gritsch, MD – A study comparing a new immunosuppressive medication to

- standard immunosuppression. The new immunosuppressive medication allows the patients to be steroid-free (many patients don't like to be on steroids), but inhibits healing, promotes delayed graft function and elevates cholesterol.
- Kidney Transplantation, Co-PI: H. Albin Gritsch, MD – The purpose of this study is to test two different combinations of medications to see if they are effective in preventing kidney transplant rejection and also to see if these combinations create fewer side effects than standard kidney transplant treatment.
- Kidney Transplantation, Reducing the Rate of Heart and Blood Vessel Disease in Stable Kidney Transplant Subjects, Co-PI: H. Albin Gritsch, MD - This study compares the effects of two separate vitamin regimens on the cardiovascular health of kidney transplant recipients over a period of five years.
- Kidney Transplantation, the Effects of Switching Kidney Transplant Patients with Diabetes from Prograf to Neoral, Co-PI: H. Albin Gritsch, MD – This study seeks to discover the effects on blood sugar levels of switching patients who are currently taking Prograf and who have developed diabetes after receiving a kidney transplant, to Neoral.
- Kidney Transplantation, PI: H. Albin Gritsch, MD - A study to evaluate new methods of monitoring the immune system in patients following renal transplantation. The goal is to detect rejection at an early stage before the new kidney is severely injured. These new techniques may reduce the need for biopsy of the kidney and may allow for less immunosuppression in some patients.

#### PROSTATE CANCER AND DISORDERS

- Prostate Cancer, PI: Robert Reiter, MD – Four-arm study of adjuvant treatment after prostatectomy for highrisk patients with either hormonal and chemotherapy or hormone alone administered as either immediate or deferred therapy (Pharmaceutical company:
- Prostate Cancer, PI: Arie Belldegrun, MD – Targeted therapy and surgery for locally advanced prostate cancer (Pharmaceutical company: Pfizer)
- Prostate Cancer, PI: Allan Pantuck, MD – A phase III study of the effects of patient-derived tumor vaccine in patients with hormone refractory prostate cancer (Pharmaceutical company: Dendreon)

- Prostate Cancer, PI: Allan Pantuck, MD Effects of pomegranate juice or extract or placebo on PSA rising after primary treatment (Pharmaceutical company: Roll)
- Prostate Cancer, PI: Allan Pantuck, MD – Chemotherapy with or without vaccine in patients with hormone refractory metastatic disease (Pharmaceutical company: Cell Genesys)
- Prostate Cancer, PI: Allan Pantuck, MD – Evaluating DN-101 (high-dose calcitrol) with or without chemotherapy in metastatic hormone-independent prostate cancer (Pharmaceutical company: Novacea)
- Prostate Cancer, PI: Arie Belldegrun, MD A study testing neoadjuvant hormonal therapy to downsize prostate prior to cryo- or brachytherapy (Pharmaceutical company: Sanofi)
- Prostate Cancer and BPH, PI: Arie Belldegrun, MD – Quality assessment of

- the Roei loop resectoscope for transurethral resection of bladder neoplasm and BPH (Pharmaceutical company: Roei)
- Prostate Cancer, PI: William
  Aronson, MD Patients who are scheduled to undergo radical prostatectomy (localized disease) are being recruited for a trial in which they are randomized to a balanced Western diet or a low-fat diet with fish oil capsules, to study serum and tissue biomarkers. The goal is to enroll all men who are scheduled to undergo radical prostatectomy at UCLA who have more than minimal disease
- Chronic Prostatitis/Chronic Pelvic Pain Syndrome (CP/CPPS) in Recently Diagnosed and/or Newly Symptomatic Alpha-blocker Naive Patients, PI: Mark S. Litwin, MD, MPH A randomized, multicenter, double-blind clinical trial to evaluate the efficacy and safety of 10mg alfuzosin in the treatment of CP/CPPS; the trial

- examines the efficacy and safety/tolerability of alfuzosin (trade name: Uroxatral), a type of prescription medicine that is called an "alpha blocker," in patients with relatively new onset of the condition.
- Prostatitis/Chronic Pelvic Pain Syndrome, PI: Mark S. Litwin, MD, MPH – A randomized, placebo-controlled, multi-center clinical trial to evaluate the efficacy and safety of pregabalin; the study investigates the efficacy and safety/ tolerability of pregabalin (brand name: Lyrica) in treating patients with CP/CPPS.
- Chronic Prostatitis: Pain, Marital and Sexual Functioning Among Men with Chronic Prostatitis/Chronic Pelvic Pain Syndrome, PI: Mark S. Litwin, MD, MPH Examines the pain, disability, adjustment and marital and sexual relationships experienced by patients with CP/CPPS and their partners/spouses.

#### **CLINICAL TRIALS FAQs #1**

What Is a Clinical Trial?

In research, a clinical trial is a study conducted with patients, usually to evaluate a new treatment. Each study is designed to answer scientific questions and to find new and better ways to help patients.

The search for good treatments begins with basic research in laboratory and animal studies. This research points out the new methods with the most potential for success and, as much as possible, shows how to use them safely and effectively. But this early research cannot predict exactly how a new treatment will work with patients. The laboratory research that achieves the most promising results is then tried in patient studies, with the hope that this will lead to findings that help many people.

With any new treatment there may be risks as well as possible benefits. There may also be some risks that are not yet known. Clinical trials help to determine if a promising new treatment is safe and effective for patients. During a trial, extensive information is gained about a new treatment, its risks, and how well it may or may not work.

Standard treatments, the ones now in use, are often the foundation for building new, better treatments through successful clinical trials. In additional to improving on what has worked in the past, trials also result in revolutionary new treatments and therapies that eventually become universally accepted.



Nazy Zomorodian, MSN, CUNP, Director of Clinical Trials

Nazy Zomorodian, MSN, CUNP Director of the General Urology Clinical Trials Office

Do you want to read more FAQs (frequently asked questions)? Go to www.uclaurology.com and click on the "Research & Clinical Trials" link.

#### **CLINICAL TRIALS PHASES**

- Phase I: These trials are the first studies on humans following the animal studies and use a limited number of patients, testing for safety and MTD (maximum tolerated dose).
- Phase II: These trials take place after Phase I, involve more patients, and check for safety and efficacy.
- Phase III: Phase III is the most wide-ranging stage. This phase involves hundreds of patients, and tests for safety and efficacy, primarily by means of randomized trials with a placebo control group. Phase III trials are usually multi-center and often international in scale.

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