Effect of Weight Loss on Prostate Cancer Pathology

UCLA Informed Consent Form

NCT#00475982

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University of California, Los Angeles

CONSENT TO PARTICIPATE IN RESEARCH

Effects of Weight Loss on Prostate Cancer Pathology

You are being asked to participate in a research study conducted by Drs. William Aronson and Zhaoping Li, from the Department of Medicine and Urology at the University of California, Los Angeles. You were selected as a possible participant in this study because you have prostate cancer and are scheduled for a prostatectomy. Your participation in this research study is voluntary

PURPOSE OF THE STUDY

Obesity is a major public health concern, and may play an important role in the risk of developing prostate cancer and the growth of prostate cancer. The purpose of this study is to determine if losing weight has an effect on substances in your blood and prostate tissue that are related to prostate cancer growth. These substances are called growth factors. Prior animal studies suggest that losing weight can lower the amount of prostate cancer growth factors in the blood and prostate tissue. This information makes it important to us to find out more about any possible connection between weight-loss and the amount of growth factors in the blood stream and prostate tissue. In addition to doing studies on your blood and prostate tissue, we also will use a small amount of genetic material (the material inside each cell that is passed on from the parent to a child) from your prostate tissue to study the effects that losing weight may have on your prostate cancer.

This is a randomized study. This means that you will be assigned to one of two groups. You will have a 1 in 2 chance of being assigned to the Control Group (No Weight-Loss) or the Weight-Loss Group. This assignment will be determined by chance. The process is similar to drawing cards or picking straws. This means your assignment to one of the groups is based on chance and not on a medical decision made by the study doctor.

PROCEDURES

If you agree to participate in this study and if you meet all of the eligibility requirements, you can expect your participation to last approximately 5-8 weeks. We are only entering subjects into this research study that are overweight. As described below, you will have your study visits at the Veterans Administration. The total number of visits will depend on whether you are placed in the Weight-Loss or No Weight-Loss Group.

If you volunteer to participate in this study, we would ask you to do the following:

First Study Visit:

You will be asked to undergo the following procedures during the first study visit:

- Medical history and physical examination
- Measurement of your height and weight
- Measurement of your waist and hips with a measuring tape
- DEXA Scan: Dual Energy X-ray Absorptiometry by a Lunar Prodigy Advance DEXA (GE Medical Systems, Waukesha, Wisconsin): This is a non-invasive test that measures the body

composition through a computerized DPX densitometer scanner. All scans are performed while the subjects are wearing light indoor clothing and no removable metal objects. Subjects lie flat on a DEXA table while the scanner passes over them. The typical scan time is 5 minutes, depending on patient height. This procedure is completely painless.

- Fasting Blood Draw: About eight teaspoons of blood (40ml) of your blood will be collected. You will be asked to fast for 10 hours prior to this blood collection. During the fasting period it is fine for you to drink plain water. We will measure the PSA, lipids, and various hormones and proteins in your blood.
- You will be given a 3-Day Food Diary form to complete over a 3-day period to determine the type and amount of food you eat.

This first study visit will take about 2 hours.

Study Phase:

No-Weight-loss Group: If you are assigned to the "No Weight-Loss Group," you will not be given instructions on losing weight. Rather you will be asked to continue your usual dietary habits. You will be given two 3-Day Food Diary form to complete. The first the week after your Screening Visit and the second to be brought in for your Final Visit prior to prostatectomy. You will be given the option of mailing this form back to the research team, or bringing it to the VA hospital at a time that is convenient for you.

You will be asked to undergo the following procedures within 3 days of your scheduled prostatectomy:

- Measurement of your weight
- Measurement of your waist and hips with a measuring tape
- Fasting Blood draw: About eight teaspoons of blood (40ml) of your blood will be collected. You will be asked to fast for 10 hours prior to this blood collection. During the fasting period it is fine for you to drink plain water. We will measure the prostatic specific antigen (PSA), lipids, various hormones and proteins in your blood.
- DEXA Scan

This study visit will take about 2 hours.

You will then be counseled on the option of participating in an 8-week weight loss program after you have recovered from your prostatectomy. If you elect to undergo the optional weight loss program, you should contact the research coordinator, Sherry Jeffery, at (310) 268-3670 to schedule your first appointment. The weight loss program will consist of 4 weekly visits with a dietician, then 2 additional visits at 2-week intervals. You will be instructed on daily meal plans that reduce the total number of calories you eat per day by 500 to 800 calories. You will also be instructed on daily exercise routines such as walking and stretching. These exercise routines will be personalized based on your capabilities and limitations. At each visit with the dietician you will be weighed, and you will be counseled on exercise routines and meal planning.

Weight-loss Group: If you are assigned to the weight-loss group, you will meet with a dietician weekly for four weeks and then every two weeks thereafter, up until the time of your prostate surgery. You will be instructed on daily meal plans that reduce the total number of calories you eat per day by 500 to 800 calories. You will also be instructed on daily exercise routines such as walking and stretching. These exercise routines will be personalized based on your capabilities and limitations. You will also be given a

pedometer (device you wear on your belt or in your pocket that measures the number of steps you take) and an exercise log to record the amount of exercise you perform each day. At each visit with the dietician your exercise logs and the readings on your pedometer will be reviewed, you will be weighed, and you will be counseled on exercise routines and meal planning. At the final visit with the dietician you will be given a 3-Day Food record form to complete during the week prior to your scheduled prostatectomy to determine the type and amount of food you eat over a 3-day period of time. You will be given the option of mailing this form back to the research team, or bringing it to the VA hospital at a time that is convenient for you. Subjects will also have the option of coming in for a study visit on weeks 5 and 7 for nutritional counseling, to review pedometer readings with the study coordinator, and to be weighed.

You will be asked to undergo the following procedures within 3 days of your scheduled prostatectomy:

- Measurement of your weight
- Measurement of your waist and hips with a measuring tape
- DEXA Scan to determine the amount of muscle, bone, and fat in your body
- Fasting Blood draw: About eight teaspoons of blood (40ml) will be collected. You will be asked to fast for 10 hours prior to this blood collection. During the fasting period it is OK for you to drink plain water. We will measure the PSA, lipids, and various hormones and proteins in your blood.

This study visit will take about 2 hours.

Date of Surgery: After your prostate is removed, the pathologist or pathology technician will examine the prostate tissue and make sure enough tissue is available to measure the amount and extent of your prostate cancer. The pathologist or pathology technician will then cut out four (4) small pieces (about one gram) of prostate tissue to be used for research by the study team. The investigators will study growth factors and genetic material in your prostate tissue that may affect prostate cancer growth. During your surgery a small sample (about a teaspoon) of fat from around your prostate and from your incision will be collected to study if the weight loss affected inflammation in your fat

Study Withdrawal: If you choose to withdraw from the study early, we would request that you allow us to take one more blood draw (eight teaspoons, 40 ml) to measure your PSA, lipids, and various hormones and proteins in your blood. The study team will evaluate if there has been any change to the usual medications you take, and will evaluate if you are having any side effects. This visit will take about 45 minutes.

POTENTIAL RISKS AND DISCOMFORTS

If any of the doctors listed on this consent form is your treating physician, he (or she) is also an investigator for this study. As an investigator, he (or she) is interested not only in your clinical welfare, but also in the results of this study. It is possible that occasionally these two goals may be in conflict. At any time during this study, you may ask for a second opinion from another doctor who is in no way associated with this study.

You may experience the following risks and discomforts as a result of participating in this research study:

Weight Loss: Weight loss may result in a feeling of fatigue, loss of strength or a decrease in your ability to perform daily functions.

Exercise: Exercise may result in injury to your joints, bones and muscles. You may experience muscle soreness in your arms or legs, joint or bone pain, sprain your joints or break your bones. You may also experience a heart attack.

Blood Drawing: When having blood drawn, you may experience some discomfort as a result of the needle prick in your arm. Some bruising or slight bleeding may occur. Although infection is possible, it is extremely rare, because the needle is sterile and disposable. Occasionally, people feel lightheaded or faint when blood is drawn.

3-Day Food Diary: This diary will require several hours to complete over a 3-day period. You may find this time commitment inconvenient.

Radiation Exposure From DEXA Scan: We are exposed to radiation on a daily basis, both from natural (sun and earth) and man made sources. In addition to the radiation that you may be exposed to as part of your clinical care (if you are receiving clinical care), you will receive two DEXA whole body scans while participating in this research study. The estimated radiation dose that you will receive as a result of these additional DEXA scans is 0.06 millirem or 0.0012% of the 5,000 millirem annual limit allowed radiation workers.

Delay of Surgery: Delaying your surgery for 5-8 weeks may also cause you some anxiety. You have the option of not participating in this trial to avoid this anxiety.

Collection of Subcutaneous Fat:

There is a small risk of bleeding or bruising at the site of the incision related to removing a teaspoon of abdominal wall fat from the site of the incision.

As with any treatment, certain food products may cause an allergic reaction. If you have allergies to food products or medicines you should tell your study doctor.

If you experience any symptoms or medical problems during your participation in the research study, please contact the research team and let them know the problems you are experiencing. In addition to the risks listed above, the treatment or procedures in this study may involve risks that are currently unforeseeable.

POTENTIAL BENEFITS TO SUBJECTS AND/OR SOCIETY

No direct benefit can be promised to you from your participation in this study. The results of this study may lead to larger studies evaluating weight-loss for treating prostate cancer and new ways to treat or prevent prostate cancer.

PARTICIPATION AND WITHDRAWL

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind.

PAYMENT FOR PARTICIPATION

There will be no payment for participation in this study. You will be compensated for your travel miles for research-related visits. After each study visit, the VA cashier will compensate you for mileage you traveled at the standard VA rate. The present rate is 48.5 cents per mile. This rate may change in the future.

FINANCIAL OBLIGATION

There is no cost for participating in this study, or for any of the tests and procedures that will be performed. Neither you nor your insurance company will be billed for your participation in this research.

EMERGENCY CARE AND COMPENSATION FOR INJURY

If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost. The University of California does not normally provide any other form of compensation for injury.

PRIVACY AND CONFIDENTIALITY

The only people, who will know that you are a research subject, are members of the research team and, if appropriate, your physician and nurses. Also, representatives of the UCLA Office for Protection of Research Subjects (OPRS) are among those individuals who may review identifiable information. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or if required by law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. All records containing personal information, research data, and related records will be stored in locked files in Dr. Aronson's West LA VA research office, Building 500, Room 6613. All data that will be collected will be assigned with a personal identification code to protect personal privacy. It will be accessible only by members of the research team named above. After all the data has been analyzed, it will be kept in storage for five years, after that it will be destroyed by a paper shredder.

GENETIC INFORMATION IN YOUR SAMPLE: POSSIBLE LIMITS TO INDIVIDUAL CONFIDENTIALITY

Every tissue or fluid sample contains genetic information. Recent studies have found normal and disease producing genetic variations among individuals. Such variations may permit identification of individual participants. Despite this possible limitation, every precaution will be taken to maintain your confidentiality now and in the future.

We have learned from past research that we will not always be able to predict future research findings and new technologies. You should be aware that unforeseeable problems may arise from new developments. Sometimes genetic information suggesting different parentage is obtained during research. We do not plan to report such findings to participants.

Within the limits imposed by technology and the law, every effort will be made to maintain the privacy of your genetic information

IDENTIFICATION OF INVESTIGATORS

If you have any questions or concerns about the research, please feel free to contact: Dr. Aronson @ (310) 268-3446 and Dr. Li at (310) 268-3528. After hours, Drs. Aronson and Li may be contacted through the UCLA Page Operator (310) 825-6301.

RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal rights because of your participation in this research study. If you have questions regarding your rights as a research subject, contact the Office for Protection of Research Subjects at UCLA, 11000 Kinross Ave., Suite 102, Box 951694, Los Angeles, CA 90095-1694, (310) 825-5344.

SIGNATURE OF RESEARCH SUBJECT

I understand the procedures described above. My questions have been answered to my satisfaction and I agree to participate in this study. I have been given a copy of this form.

_____
Name of Subject

_____ _____
Signature Subject Date

SIGNATURE OF INVESTIGATOR OR DESIGNEE

In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____
Name of Investigator or Designee

_____ _____
Signature of Investigator or Designee Date (must be the same as subjects)