BAPTIST MD Anderson Cancer Center
Making Cancer History®

Participant Informed Consent Form

Study Title:
Testing less intensive treatment for selected low-risk patients with oropharyngeal cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Pilot Feasibility Trial Of Dose Volume Adjusted Chemoradiotherapy In Hpv-Associated Oropharyngeal Cancer Of The Elderly (DACHOC-E)

Study Doctor:
Omar Mahmoud, MD
(904) 202-7300

Baptist MD Anderson Cancer Center
1301 Palm Avenue
Jacksonville, FL 32207

INTRODUCTION

Standard Approach To Your Type Of Cancer

You are being asked to take part in this study because you have HPV associated oropharyngeal cancer of a that appears to be more sensitive to radiation treatment. People who are not in a study are usually treated with high doses of radiation and chemotherapy. For patients who receive the usual approach for this cancer, about 85 out of 100 are alive and free of cancer at 2 years. These treatments can result in many side effects both during and after treatment. Your doctor will discuss these with you.

Treatment Alternatives

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

Purpose Of This Study

Previous studies of your type of cancer have shown high rates of cancer control but result in many short- and long-term side effects when treated with high dose radiation and chemotherapy. Recently, investigators have noticed similar high rates of cancer control in small numbers of patients who receive less intensive treatments using lower doses of radiation, smaller radiation fields with chemotherapy. It is expected that the side effects of treatment with lower doses of

radiation would be less. For this reason, this study is looking at a different regimen of reducing the intensity of your treatment.

The purpose of this study is to compare any good and bad effects of using lower dose smaller fields radiation therapy and chemotherapy with published outcomes. This study will allow the researchers to know whether these different approaches are better, the same, or worse than the usual approach. To be better, the study approach should result in the same survival rate of the usual approach (about 85 out of 100 patients alive and free of cancer at 2 years) but with less long term side effects.

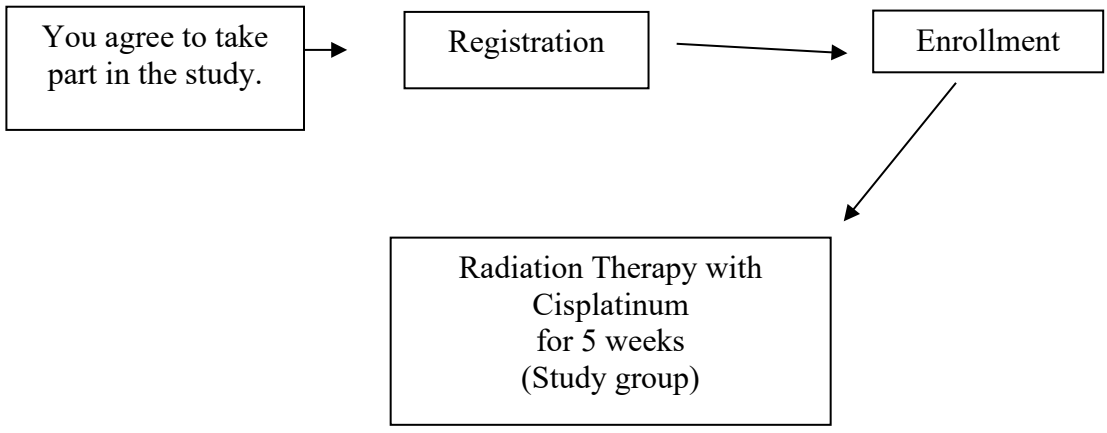
There will be about 20 people taking part in this study.

Study Treatment Groups
This study has one study group.

All the people on the study will receive radiation therapy once a day, 5 days a week (for a total of 55 Gy over 5 weeks) and chemotherapy, cisplatin, (given through the vein for about 30-60 minutes) once a week for 5 weeks. Medications and saline solutions to prevent side effects of chemotherapy may also be given by vein and may prolong your time in the chemotherapy clinic to as much as 4-6 hours.

Patients who are not on study receive a standard regimen with radiation therapy and chemotherapy, cisplatin in a schedule of 5 treatments a week for a total of 69.96 Gy over 6.5 weeks.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



Study Duration
All the patients will receive radiation for 5 weeks. After you finish treatment, your doctor will continue to watch you for side effects, check your disease, and see you in follow-up visits at 1 month after treatment, every 3 months for years 1 and 2, every 6 months for years 3, 4, and 5, then once a year for your lifetime.

Study Procedures
Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra tests, and procedures that you will need to have if you take part in this study.

1. Your privacy is very important, and the researchers will make every effort to protect it. Your test results will be identified by a unique code, and the list that links the code to your name will be kept separate from your samples and health information.
2. Before you begin the study, you are required to fill out a form with questions about your swallowing abilities. It will take you 5-10 minutes.

Possible Risks From Taking Part In This Study
If you choose to take part in this study, there is a risk that:

- The study approach may not be better, and could possibly be worse, than the usual approach for your cancer.
- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The tables on the following pages show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects Of Cisplatin

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, more than 20 and up to 100 may have:
• Nausea, vomiting • Infection, especially when white blood cell count is low • Anemia, which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Kidney damage, which may cause swelling, may require dialysis • Hearing decrease, including ringing in ears • Numbness, tingling, or pain of the arms and legs

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, from 4 to 20 may have:
• Allergic reaction, which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Confusion • Difficulty with balance

RARE, AND SERIOUS In 100 people receiving Cisplatin, 3 or fewer may have:
• Cancer of bone marrow later in life caused by chemotherapy • Seizure

The following possible risks apply to all patients who are tested and receive the usual treatment for their head and neck cancer, whether they take part in this study or not. All patients that are being treated with modern radiotherapy and are being followed for their head and neck cancer will be exposed to the doses of radiation described below. Overall, the doses of radiation that are being discussed below are very small compared to those that will be delivered to head and neck chest as part of the usual radiotherapy treatment.

Possible Side Effects Of Research Radiation Therapy

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, more than 20 and up to 100 may have:
• Reddening, tanning, or peeling of the skin, which may be permanent • Mild pain • Hair loss in the area of radiation, which may be permanent • Tiredness • Weight loss • Sores in the mouth and throat, which may be painful especially when swallowing • Cavities, tooth decay, loss of teeth, tooth sensitivity • Dry mouth, changes in taste, thick saliva, reduced sense of smell—may be permanent • Pain or pressure in the ear

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, from 4 to 20 may have:
• Decrease in function of the thyroid gland that may require you to take thyroid replacement medicine • Damage to the nerves of the shoulder and arm, which may cause decreased movement and feeling • Ear infection • Hearing loss • Difficulty swallowing, which may require a long term or permanent feeding tube

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Breathing and swallowing problems that may require a surgical procedure to create an opening through the neck into the windpipe • Damage to the nerves in the head and neck that control sensation, expression, or other motor functions • Damage to the jawbone, which may cause jaw pain and loosening of teeth • Damage to the voice box or nerves to the voice box, which may cause hoarseness, shortness of breath, inability to speak • Damage to the skin, soft tissues, or other parts of the head and neck that may require a major operation to correct and, rarely, can be life threatening • Damage to the spinal cord, which may cause permanent weakness

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Possible Benefits Of Taking Part In This Study
It is not possible to know at this time if the study approach is better than the usual approach, so this study may or may not help you. This study will help researchers learn things that will help people in the future.

Stopping Your Participation In This Study
You can decide to withdraw your consent for this study at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study if:
- your health changes and the study is no longer in your best interest
- new information becomes available
- you do not follow the study procedures

- the study is stopped by the study doctor, IRB, or FDA.

Your Rights In This Study
Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Baptist Health Institutional Review Board at (904) 202-2127 or email Baptist.IRB@bmcjax.com.

Anticipated Expenses/Compensation
Your tumor may have been tested by your doctor previously, which is usually billed to your insurance. You and your insurance company will be responsible for the cost.

You and/or your health plan/insurance company will need to pay for the costs of radiation therapy and chemotherapy while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

Your doctor may recommend that you have a PET/CT scan before starting treatment or during treatment. You and/or your health plan/insurance company will need to pay for the costs of the PET/CT scans, including the cost of tests, procedures, or medicines to manage any side effects. Before you have these scans, it is advised to check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

Injury As A Result Of Taking Part In This Study
If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study staff will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Confidentiality And Release Of Information
The study doctor and research team will use health data about you, called protected health information (for example, name, address, medical history), to conduct this study, as described in this consent form. This health data may come from your family doctor or other health care workers.

Only certain people have the legal right to review these research records, and they will protect the confidentiality of these records as much as the law allows. These people include researchers for this study, certain Baptist Health System officials, the hospital or clinic involved in this research, and the Baptist Institutional Review Board (IRB). An IRB is a group of people that ensures the

rights and welfare of research participants are protected. Otherwise, your research records will not be released without your permission unless required by law or a court order.

Your protected health information may be collected, used, and shared with others to determine if you can take part in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current, or future health or study records, from procedures such as physical examination, x-rays, blood or urine tests, or from other procedures or tests. More specifically, the following information may be collected, used, and shared with others:

- Your name, address, telephone number, date of birth, race/ethnicity, medical record numbers, and/or other identifying information
- Complete past medical history
- Information about sexually transmitted diseases
- Information about other infectious diseases that must be reported to Public Health authorities
- Records of physical exams
- Laboratory, x-ray, MRI, and other test results
- Diaries and questionnaires
- Records about study medications or drugs
- Autopsy report or death certificate, if available
- Your images, video, and voice recordings
- Your social security number for compensation purposes

Your protected health information may be collected, used, and shared with others by:

- The Baptist Health IRB
- The study doctor and the research staff associated with this study.
- Other professionals in the Baptist Health System that provide study-related treatment or procedures.
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and Federal, State and local health departments.
- Your insurance company, for purposes of obtaining payment.

Information collected about you and your health will be stored in locked areas or in computers with security passwords.

If you agree to be in this research study, it is possible that some of the information collected might be copied into a "limited data set" to be used for other research purposes. If so, the limited data set may only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, or any other photographs, numbers, codes, or so forth that link you to the information in the limited data set. If

used, limited data sets have legal agreements to protect your identity and confidentiality and privacy.

It is the intent of the study doctor and study staff that the health data (as described above) will not identify you. Instead, it may include your initials, date of birth, and study visit dates. Some study data may contain information that could be used (maybe in combination with other information) to identify you (for example, your date of birth). If you have questions about the specific health information that will be used in this study, you should ask the study staff.

Once this information is collected, it becomes part of the research record for this study.

In general, presenting research results helps the career of a scientist. Therefore, the study doctor or other researchers may benefit if the results of this study are presented at scientific meetings or published in scientific journals. You will not be identified by name in any published reports about this study or in any other scientific publication or presentation.

If you think that you were harmed from being in the study, the study team may also share health data about you with your insurer to resolve your claim.

Your protected health information may be collected, used, and shared with others to make sure you are eligible to take part, to carry out, and to evaluate the results of the research study. More specifically, your protected health information may be collected, used, and shared with others for the following study-related purpose(s):

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- To develop new tests.
- To other activities (such as development and regulatory) related to the study drug.
- To allow outside researchers to use clinical data that does not identify you.

For these uses, the research team may share this health data with others involved in these activities, as long as they agree to only use the health data as described here. They may transfer health data about you from your country to other countries where the privacy laws may not as strict. Once the research team shares health data about you with others, it may no longer be protected by privacy laws.

Under a new Federal Law, researchers cannot collect, use, or share any of your protected health information for research unless you allow them to by signing this consent and authorization.

Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use, and sharing of your protected health information by signing this consent/authorization.

You have the right to review and copy your protected health information. However, you may not be allowed to do so until after the study is finished.

There is a risk that information received by authorized persons could be shared with others beyond your authorization and not covered by the law.

There is a risk that if people other than the research team may get your health data, they could misuse it for purposes other than those outlined in this consent. The research team has strict privacy and confidentiality protection procedures in place to prevent this from occurring so the chance of this happening to you is extremely small.

Your permission to use and share health data about you will not end. You may take away your permission to use and share health data about you at any time by contacting the study doctor. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after that date. However, health data about you that has already been gathered may still be used and given to others as described in this form.

You may not be able to review some of your records related to the study until after the study has been completed. When the study is over, you may contact in writing to the study doctor to see your health data from the study and to correct any errors. Results obtained from planned genetic and biomarker research will not be provided back to you or the study doctor.

Communication With Providers Regarding Study Participation
It is important that any medical provider or other medical professional who provides consultation and care for your medical needs, are aware that you are participating in this clinical trial. This communication will ensure that you are not prescribed any medication that might be prohibited by the study and that proper medical care is provided according to the study. It is important that your welfare comes first and that we ensure your safety at all times. If there is medical care needed that is not part of the study or prohibited by the study, you may be removed from study participation.

We will communicate your clinical trial participation to those medical providers you identify to us. We are also asking that you notify any medical provider or other medical professional at each visit that you are participating in this study. If there are any questions, the study doctor listed on the first page of this informed consent form can be contacted.

Once you agree to participate in this study and are enrolled into the study, your Baptist Health medical record will be flagged to indicate you are participating in a clinical study. This will help to ensure any Baptist Health provider knows you are a study participant. It is still important that you communicate with Baptist Health providers and providers outside Baptist Health of your study participation.

Additional Information
You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Contact Information For Questions About This Study

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor, Dr. Omar Mahmoud, at (904) 202-7300.

Participant Informed Consent Signature Page

By signing this consent form, you agree to the following:

- You have read and understand the statements in this informed consent form.
- You have had the opportunity to ask questions and are satisfied with the explanations provided.
- You voluntarily agree to take part in this study.
- You understand that you and/or your legal representative will receive a copy of this signed and dated written consent form.
- By signing this form, you are not giving up any of your legal rights.
- You understand your personal doctor(s) may be contacted to obtain details of your medical history and to notify him/her of your participation in this study.

_____
Patient's Printed Name

_____ _____
Patient's Signature Date/Time

_____
Printed Name of Legally Authorized Representative (LAR) (*if applicable*)

_____ _____
Signature of Legally Authorized Representative (LAR) Date/Time

_____ _____
Printed Name and Signature of Person Obtaining Consent Date/Time

_____ _____
Printed Name and Signature of Study Doctor Date/Time