MC1273 / 12-005272

Phase II Evaluation of Adjuvant Hyperfractionated Radiation and Docetaxel for HPV Associated Oropharynx Cancer

NCT01932697

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MAYO CLINIC

Name and Clinic Number

Approval Date: **June 5, 2017**
Not to be used after: **June 4, 2018**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1273, Phase II Evaluation of Adjuvant Hyperfractionated Radiation and Docetaxel for HPV Associated Oropharynx Cancer (Mayo Clinic Arizona)

IRB#: 12-005272

Principal Investigator: Dr. D. J. Ma and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigators: Dr. Samir H. Patel (Mayo Clinic Arizona)	**Phone:** (480) 301-8120 **Address:** Mayo Clinic Arizona 13400 E. Shea Blvd. Scottsdale, AZ 85259	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Research Billing	**Arizona:** (800) 603-0558	▪ Billing or insurance related to this research study

Other Information:

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

A description of this research study will be available on http://clinicaltrials.mayo.edu/ . This website will not include information that can identify you. You can search this website at any time.

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have head and neck cancer that after surgery has a risk of recurring without treatment. The standard treatment of surgery (which you have had or will have) followed by radiation therapy can stop tumors from growing in the head and neck region in most people. However, the cancer can recur or can spread to other parts of the body.

2. Why is this research study being done?

The purpose of this study is to determine the effects of radiation therapy and docetaxel on you and your cancer. Docetaxel is a drug that may delay or prevent tumor growth by blocking certain cellular chemical pathways that lead to tumor development.

The purpose of this is to evaluate a new treatment being developed for head and neck cancers such as yours. This study will evaluate the effectiveness and side effects of a less intense course of radiation and chemotherapy.

Docetaxel is approved by the Food and Drug Administration for the treatment of Head and Neck cancers with radiation therapy.

3. Information you should know

Who is Funding the Study?

Funding for this study came through the assistance of a generous benefactor.

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Conflict of Interest:

- This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.
- Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the Financial Conflict of Interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this Financial Conflict of Interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.
- Additional information is available to any interested study participant regarding the details of this Financial Conflict of Interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at 507-284-0075.
- One or more of the investigators associated with this project and Mayo Clinic have a Financial Conflict of Interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.

4. How long will you be in this research study?

You will be in the study for about 5 years.

5. What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

After signing this consent form you will be asked to have a small amount of blood drawn. This blood will then be stored and not used until after you have completed surgical removal of your tumor and testing of that tumor reveals that you qualify for the main part of this study. If your tumor sample qualifies you for the main study your blood sample will be used to look for genetic markers in your blood. Two more blood samples will be drawn in the main study for comparisons of these markers. This blood draw will be covered by the research study and is optional.

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Assessment of tumor tissue removed during your surgery to see if you have the risk factors required in this study
- Physical examination by several doctors
- Evaluation of your ability to carry out daily activities
- A chest x-ray or chest CT (Computed Tomography) scan or chest CT/PET (Positron Emission Tomography) scan
    - A CT scan is a study using x-rays to look at one part of your body.
    - A PET scan is a computerized image that looks at the activity of tumor cells in your entire body and that requires injection of a special marker into your vein, such as sugar (glucose) combined with a low-dose radioactive substance (a tracer). A camera records the tracer's signal as it travels through your body.
- Blood tests (about 2 teaspoons of blood will be taken from your vein)
- A serum pregnancy test 7 days prior to registration, for women able to have children
- A dental evaluation before receiving radiation
- An evaluation of your ability to chew and swallow
- Quality of life questionnaires
- If your study doctor recommends:
    - Examination of the back of your throat and voice box (larynx) with a mirror and/or a flexible lighted tube inserted through your mouth by an ear, nose and throat specialist or by a head and neck surgeon; this examination may be done in an office or may need to be done in the hospital under general anesthesia. The specialist or surgeon will talk with you about this procedure.
    - A CT scan with contrast (contrast means that dye is injected into your vein to increase the differences between normal and abnormal tissue), or a CT/PET scan and/or an MRI of your head and neck (Magnetic Resonance Imaging or MRI is imaging that uses a strong magnetic field to look at one part of your body).
    - An evaluation of your diet to see if a feeding tube is needed

<u>During the study</u>:

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

You will receive 10 days of radiation therapy. Along with that you will be given docetaxel on days 1 and 8. Prior to taking the docetaxel you may be given dexamethasone the day before, the day of docetaxel, and the day after to minimize side effects.

Weekly during radiation plus docetaxel:

- A physical examination by several doctors
- Evaluation of your ability to carry out daily activities
- Evaluation of any side effects from treatment you may be having
- A blood test

For All Subjects: At 14 days after you finish radiation therapy:

- A physical examination by several doctors
- Evaluation of your ability to carry out daily activities
- Evaluation of any side effects from treatment you may be having
- A blood test

If your study doctor recommends:

- CT scan with contrast, or CT/PET scan, and/or MRI of your head and neck
- A chest x-ray or chest CT scan or chest CT/PET scan
- A biopsy to check for recurrence of the cancer
- Quality of life questionnaires

You will need these tests and procedures in follow-up visits:
They are being done to see how you and your cancer was affected by the treatment you received. These tests and procedures are part of regular cancer care.

For All Subjects: At one month after you finish radiation therapy:

- A physical examination
- Evaluation of your ability to carry out daily activities
- Blood tests (about 1 teaspoon of blood will be taken from your vein)
- An evaluation of your ability to chew and swallow
- Evaluation of any side effects from treatment you may be having
- If your study doctor recommends: Examination of the back of your throat and voice box (larynx) with a mirror and/or a flexible lighted tube inserted through your mouth
- Quality of life questionnaires

For All Subjects: Every 3 months from the end of radiation therapy for 2 years, every 6 months for year 3, then once a year for years 4 and 5:

- A physical examination
    - Evaluation of your ability to carry out daily activities
    - Evaluation of any side effects from treatment you may be having
    - If your study doctor recommends:
        - Examination of the back of your throat and voice box (larynx) with a mirror and/or a flexible lighted tube inserted through your mouth
        - A CT scan with contrast, or CT/PET scan, and/or MRI of your head and neck

For All Subjects: At 12 months from the end of radiation treatment

- An evaluation of your ability to chew and swallow

For All Subjects: At 3, 12, and 24 months from the end of radiation treatment

- Quality of life questionnaire

For All Subjects: Once a year for 5 years:

- A chest x-ray or chest CT scan or chest CT/PET scan

For All Subjects: If recommended by your study doctor:

- A biopsy to check for recurrence of the cancer
- Blood tests (about 1 teaspoon of blood will be taken from your vein)
- Evaluation of any side effects from treatment you may be having

Quality of Life Study:

We want to know your view of how your life has been affected by cancer and its treatment. This "Quality of life" study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at your diet and your ability to chew, swallow, speak clearly, and looks at any changes to your skin.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

You will be asked to complete 5questionnaires at the following times: Before you begin treatment and at 1, 3, 12, and 24 months from the end of your radiation therapy. It takes about 5-10 minutes to fill out each questionnaire.

6. What are the possible risks or discomforts from being in this research study?

Risks Associated with Radiation to the Head and Neck:

Likely

- Sores in the mouth and/or throat which can be painful and make it very difficult to chew and or swallow foods
- Mouth dryness or changes in taste and/or smell that may be permanent
- Thick saliva
- Hoarseness
- Tanning or redness, drying and/or irritation of the skin in the head and neck area being treated with radiation
- Ear pain and/or pressure
- Fatigue
- Weight loss
- Permanent hair loss in the area treated with radiation (face, chin, neck)
- Loss of teeth, or cavities in the teeth, if strict dental care is not followed and/or hypersensitivity of teeth

Less likely

- Decrease in function of the thyroid gland that may require you to take thyroid replacement medicine to prevent you from feeling tired or sleepy
- Temporary pain or scarring around nerves in the shoulder that could cause numbness and/or weakness
- Breathing problems
- Difficulty with swallowing and eating for which you might need a long term or permanent feeding tube; possibility of inhaling food and/or liquids into the lungs – which could also result in pneumonia.
- Serious ear infections and/or hearing loss
- Feeling sick to the stomach (nausea)
- Throwing up (vomiting)
- Headache

Rare but serious

- Serious damage to the nerves in the neck, jawbone, voice box, skin, or other parts of the head and neck that may require a major operation to correct and, rarely, can even be life threatening
- Damage to the spinal cord leading to permanent weakness and/or symptoms like a "stroke"
- Seizures, coma, and lower white blood cell and platelet counts raising the risk of infection and bleeding. Radiation therapy at these dose levels also may cause damage to normal brain, but this is rare. Specific effects depend upon the location of the area(s) of damage but may be a decrease in judgment, memory, emotions, vision, hearing, sensation, or ability to control movement.

Although every effort will be made to minimize the risk of side effects, the possibility that they may occur cannot be eliminated. Side effects resulting from radiation therapy, when used in combination with chemotherapy, can be severe, or in rare cases, fatal. These side effects may be long-lasting or even permanent.

Risks associated with Docetaxel:

Likely risks of Docetaxel (Taxotere) *(events occurring greater than 20% of the time)*

- Decrease in white blood cell count, which may increase the risk of infection, decreased healing, and/or bleeding
- Decrease in red blood cell count, which may result in anemia, tiredness, and/or shortness of breath
- Tiredness and/or general weakness
- Unusual sleepiness
- Sick to stomach or throwing up (Nausea and/or vomiting)
- Mouth sores
- Loose stools (Diarrhea)
- Loss of appetite, change in taste, and/or weight loss (Anorexia)
- Loss of hair (Alopecia
- Headache
- Shortness of breath
- Muscle or joint pain
- Changes in the nails
- Inflammation of the eyes
- Loss of feeling or numbness and tingling in fingers and toes
- Irritation or loss of skin of the hands or soles of the feet

Less likely risks of Docetaxel (Taxotere) *(events occurring less than or equal to 20% of the time)*

- Rash, redness and/or swelling of the skin
- Allergic reactions, which may involve rash, fever, swelling, chills, or low back pain
- Watery eyes
- Inflammation of veins
- Irregular heartbeat
- Lowered platelet count, which may increase risk of bleeding
- Seizures
- Liver inflammation, which may result in yellowing of skin and eyes
- Pain in the upper right of the stomach area
- Swelling of feet
- Increased fluid around the lung and heart, which may result in shortness of breath

Rare but serious risks of Docetaxel (Taxotere) *(events occurring less than 2-3% of time)*

- Lung inflammation, which may involve shortness of breath, cough, and/or fever
- Permanent bone marrow damage that could result in leukemia
- Liver failure
- Hole in the intestine that could require surgery
- Death

The following side effects have been reported for subjects taking part in other Docetaxel (Taxotere) research studies. It is not known if these side effects were related to the Docetaxel (Taxotere)

- Heart Failure
- Low or high blood pressure
- Hearing problems
- Kidney failure

Risks Associated with Docetaxel and Radiation Therapy:

The combination of docetaxel with radiation therapy could increase the likelihood and/or severity of the side effects of radiation therapy.

Risks of drawing blood

The risks of drawing blood include pain, bruising, or rarely, infection at the site of the needle stick.

Standard of Care risks
Your doctor will discuss the risks of tests and procedures that are part of your standard clinical care.

Pregnancy and Birth Control:

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

You must use birth control for the entire study and for at least 6 months after your last dose of study drug.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

9. What are the possible benefits from being in this research study?

This study may not make your health better and may not be as good as standard of care treatment. However, the side effects from this new treatment may be less than the side effects of conventional treatment. This could mean less pain, less problems swallowing, and a lower risk of needing a feeding tube.

10. What alternative do you have if you choose not to participate in this research study?

If you choose not to participate in this research study, you can choose to receive the standard course of radiation and chemotherapy. You may choose not to receive any treatment or you could pursue treatments offered through other research studies. Talk to the Principal Investigator or your doctor if you have any questions about any treatments or procedures that are available to you.

11. What tests or procedures will you need to pay for if you take part in this research study?

The tests needed for this study are standard tests for patients with head and neck cancer and should be covered by most major insurers.

You and/or your insurance will need to pay for all tests and procedures that are part of this research study. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. You will have to pay for any costs not covered by your insurance.

If you have billing or insurance questions call Research Billing at the telephone number provided in the Contact Information section of this form.

12. Will you be paid for taking part in this research study?

No payment will be given for taking part in this study.

13. What will happen to your samples?

Your samples will be used for this study. When the study is done, they will be destroyed.

14. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

All medical information will be labeled with a code. Only Mayo has the information that matches the code to identifying information, such as your initials, birth date or medical record

number. Mayo will keep the information that matches the code to this identifying information in a safeguarded database. Only very few, authorized people, who have specifically agreed to protect your identity, will have access to this database. All other researchers and personnel, including those who will be working with your samples and medical information, will not have access to any information that can be used to identify you.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

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Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

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ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature