

Title:

Effect of Esophageal Sparing IMRT on Patient-Reported Dysphagia Outcomes in Non-Small Cell Lung Cancer Patients Receiving Radical Radiotherapy, With or Without Chemotherapy

Short Title:

Effect of Esophageal Sparing IMRT on Patient-Reported Esophageal Toxicities in Lung Cancer Patients Treated With Radiotherapy With or Without Chemotherapy

Introduction

We invite you to participate in a research study titled “Effect of Esophageal Sparing IMRT on Patient-Reported Dysphagia Outcomes in Non-Small Cell Lung Cancer Patients Receiving Radical Radiotherapy, With or Without Chemotherapy.” You are being invited to participate in this study because you have been diagnosed with cancer arising from the lung and your treatment will be done with radiotherapy. Details of this research are provided in this document. Please read it carefully. Ask questions about anything you do not understand or about which you would like more information.

Purpose of the Study

When radiotherapy is given to lung cancer patients, the normal organs located inside the chest may also receive high doses of radiation. Because of this dose, patients may experience various side effects. The esophagus (food pipe) is one of these organs. Therefore, difficulty in swallowing and heartburn caused by radiation are among the common acute side effects of radiotherapy.

IMRT (Intensity Modulated Radiotherapy) is an advanced treatment technique in which the dose reaching these organs is reduced with the help of computer-based advanced planning. Through the technique we are going to use (Esophageal Sparing IMRT), we will attempt to further reduce the exposure of the esophagus (food pipe) so that these symptoms may be reduced further.

During the Study

During the study, patients receiving radiation will be assessed every week. During radiation treatment, physician-reported and patient-reported swallowing difficulties will be recorded every week in the review clinic.

No additional or new treatment will be given to you in this study. We will try to determine the rate of patient-reported and physician-reported moderate to severe radiation-induced swallowing difficulty in patients with non-small cell lung cancer receiving concurrent chemoradiotherapy, sequential chemoradiotherapy, or radical radiotherapy.

We will also try to determine when patient-reported moderate to severe swallowing difficulty develops during radiotherapy for lung cancer. As part of this study, we would also like to collect more details regarding the side effects you experience during treatment. We will do this in two ways — one method will be a questionnaire that you will need to fill every week during treatment, and the second method will be a form that the doctor will complete each week during your visit.

What Will I Have to Do to Participate?

1. First, we will ask you to read and understand this consent form and ask any questions related to the procedure.
2. You will undergo radiotherapy planning through a CT scan (Computed Tomography Scan).
3. We will calculate the best possible dose with the help of a computer system.
4. Every week during radiotherapy, a doctor will ask you about the side effects you are experiencing. You will be given a set of questions in which you will need to answer about the swallowing difficulty and heartburn experienced during treatment.
5. After completion of treatment, you will remain on follow-up at regular intervals.

What Are the Alternatives to Participation?

You may choose not to participate in the study. This will not affect your treatment in any way.

What Are the Possible Risks?

We do not expect any additional risks in this study.

What Is the Cost of Participation?

There is no additional cost involved in this study. You will not be charged any extra money for participating in the study.

Will Any Compensation Be Provided?

There is no plan for compensation as part of this study.

What Are the Possible Benefits?

This study will help us identify the occurrence, duration, and severity of radiation-induced swallowing difficulty with the use of Esophageal Sparing IMRT (Intensity Modulated Radiotherapy), which may allow timely assessment, better supportive care, and reduction in treatment-related toxicities.

Will My Data Be Kept Confidential?

Yes. The data provided by you will be securely stored and anonymized at Tata Medical Center and will only be accessible to the doctors and nurses involved in your care. It will not be used to identify or disclose your identity and will not be shared without prior permission.

Compensation for Injury/Harm

Since this study does not involve any new intervention, no compensation will be provided for any side effects. The cost of treatment of side effects will have to be borne by the patient.

Participation

Participation in this research is voluntary. If you do not wish to participate, you may withdraw your name at any time. Your decision to participate or not participate in the study will not affect your right to receive proper treatment. You will be given a copy of this Participant Information Sheet and Consent Form for your records.

Contact Us

Tata Medical Center
Phone: 033-6605-7000

If you have any questions about the study at any time, you may contact the following investigators:

Dr. Tapesb Bhattacharya
Dr. Moses Arun Singh
Dr. Urvashi Thakur

Address: Tata Medical Center, 14 MAR (E-W), Newtown Action Area 3
Phone: 033-6605-7000, 033-6605-7404

For concerns related to the Tata Medical Center Institutional Review Board (TMC-IRB), contact 03366057579. The Director of TMC is the appellate authority.

Consent

I understand the information given above and agree to participate in the trial.

Patient Signature: _____

Name: _____

Date: _____

Investigator Signature: _____

Name: _____

Date: _____

Witness Signature: _____

Name: _____

Date: _____