Phase II Randomised Controlled Trial of Postoperative Intensity Modulated Radiotherapy(IMRT) in Locally Advanced Thyroid Cancers

Head Neck Oncology

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INFORMED CONSENT FORM

Phase II Randomised Controlled Trial of Postoperative Radiotherapy in Locally Advanced Thyroid Cancers

Summary

This trial deals with cancers of the thyroid gland which are advanced at the local site of thyroid. These cancers are treated with operation and complete removal of the thyroid gland. But due to advanced nature, there is risk of re-occurrence. Radiotherapy (use of a type of X-rays) can be used to prevent this re-occurrence. This study will study the effect of radiotherapy in preventing re-occurrence and its side effects.

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You are invited to participate in a research study (prospective randomised controlled trial) that is being done to find out whether treating you with radiation therapy after your thyroid surgery will improve your overall outcome of the disease or has any significant side effects.

Information: Surgery, when possible offers the best chance of cure for cancer of the thyroid gland. Surgery basically involves removal of the thyroid gland along with removal of the lymph nodes which drain the gland. After surgery most patients will receive radio-iodine treatment to diagnose and treat any spread of the cancer in your body. However, in advanced thyroid cancers (like yours); there is a chance of re-occurrence of the cancer in the neck. This may then lead to repeated surgeries which may also involve removing portions of your voice box and food pipe. You may therefore develop and discomfort or inability to eat or speak.

Radiation therapy can be given to the neck along with radio-iodine therapy to decrease these re occurrences of the cancer. A number of studies have shown a benefit with the use of radiation therapy in advanced cases of thyroid cancer. However, the side effects of radiation, if any, have not been well documented. This study is being done to assess the impact of radiation on the outcome of cancer and the exact side effects of radiation therapy. If the side effects are not too many, then radiation therapy can be used to decrease the chances of recurrence in the neck after thyroid. We would like to invite you to our randomized trial for patients with operated advanced thyroid cancer and radioiodine therapy, being considered for radiation therapy.

Study Plan: If the tests and procedures show that you can be in the study, and you choose to take part, then you will be included in the study. In the study, after you have completed your surgery, you will receive radio-iodine treatment as per guidelines, 6-8 weeks after surgery. You will then be randomised in one of 2 arms. One arm of this study will receive radiation therapy about 8-10 weeks after completion of initial surgery. The duration of this radiation therapy will be approximately 45 days. The other arm of the study will receive no further treatment after surgery and radio-iodine therapy. Randomization is a process similar to tossing a coin and is based on a list of numbers generated from a computer. You have an equal chance of undergoing either form of treatment: radiation or no radiation.

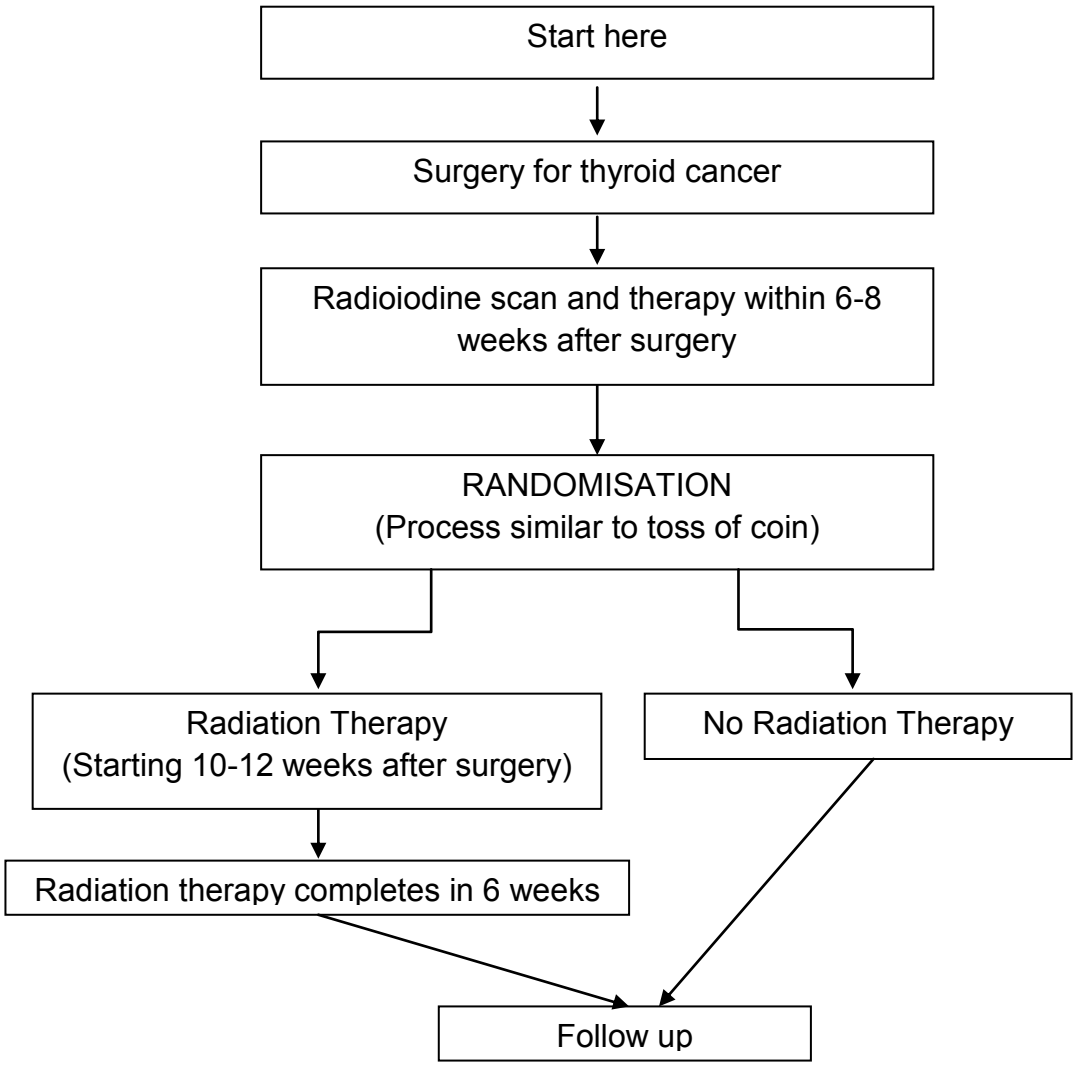
Radiation therapy will involve taking rays from a machine for 2-5 minutes per day for 5 days in a week (Monday-Friday). This procedure in itself is painless. We will assess you on a weekly basis to assess if you have any side effects of the treatment.

In both arms, once you complete the treatment you can go home and come for a follow up for after three months. You will have to follow up once every 3 months for the first two years and 6 monthly thereafter.
On every follow up visit, a detailed examination will be performed by the doctor. Twice a year you will undergo a sonography of your neck and blood tests to check if there is any re-occurrence of your cancer. At the end of two years, those of you in

the radiotherapy arm will have to undergo a swallow test called a barium swallow to see if there are any swallowing disturbances. You will have to fill a quality of life questionnaire at every visit before and after your treatment. This questionnaire will help us understand the effects which the treatment given to you has had on your life.

Potential risks and complications: The patients who are in arm one (radiation therapy arm) may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. Those of you may have the well-known side effects of radiation therapy like burning sensation in the neck, difficulty in swallowing, darkening of your neck skin, and dryness of your mouth. Not more than 6-8 % of patients (i.e. 6-8 patients in 100 patients) suffer severe side effects which may need the radiation therapy to stop. We will provide all care required if you develop any of these side effects. Most of these symptoms subside 6-8 weeks after completion of radiotherapy. There may however be some long term side effects of radiation like dryness of mouth and difficulty in swallowing. You should talk to your study doctor about any side effects that you have while taking part in the study.

Study Plan



Benefits: You may not receive any direct benefit from this study apart from being in a structured study protocol. However, the results of this study may help increase the knowledge about the treatment of this disease and this may benefit patients in future.

Confidentiality: The information in the study records will be kept confidential and the clinical charts will be housed in the Tata Memorial Hospital (TMH) /Central Research Secretariat (CRS). Data will be stored securely and will be made available only to persons conducting the study unless you specifically give permission in writing to do otherwise. No reference will be made in oral or written reports, which could link you to the study.

Compensation: You will not be paid or compensated for participating in this study. For those in the radiotherapy arm, radiation therapy will be provided to you free of cost. The cost of other treatment for cancer of the thyroid gland will have to be borne by you, irrespective of whether you are in the study. If you withdraw from the study prior to its completion, you will receive the usual standard of care for your disease, and your non-participation will not have any adverse effects on your treatment. Though serious side-effects are not expected, if you suffer from any side-effects due to the study drug and require admission for the same, the cost of the treatment will be borne by the study funds.

Contact: If you have any questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study) you may contact the researcher, Dr GH Pantvaidya at the Office No.1230, 12th Floor, Department of Surgical Oncology, HomiBhabha Block, Tata Memorial Hospital, Tel no 022-24177000, extension 7177. If you have any questions about your rights as a participant, you may contactthe member secretary, IRB I Dr. JV Divatia, or member secretary IRB II, Dr. Siddharth Laskar, Tata Memorial Hospital, Tel. No 022-24177262.

Participation: Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at any time without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed, your data will not be entered in the project report.

CONSENT

I have read the above information / I have been explained the above and agree to participate in this study. I have received a copy of this form.

Participant's name: _____

Participant's signature/thumb impression: _____

Tel no: _____ Date: _____

Impartial Witness' name: _____

Impartial witness's signature/thumb impression: _____

Tel no: _____ Date:_____

Consent administered by_____

Signature: _____ Date:_____