

INFORMATION SHEET

(for all subjects)

Research Title:

Prevention of Trismus in Head and Neck Cancer Patient Undergoing Radiotherapy: A Randomized Controlled Trial

Introduction:

You are invited to participate in a research study. Before participating in this study, it is essential that you take time to read and understand the information in this Information Sheet.

Purpose of Study:

Head and Neck Cancer (HNC) is a common cancer in Malaysia. Radiotherapy is one of the treatment modalities in treating HNC. It is well known that radiotherapy in the head and neck region might cause restriction in the mouth opening, called trismus. This study will address the issue of trismus after radiotherapy treatment. Mouth opening limitations might affect patients' quality of life regarding the ability to eat and care for oral hygiene.

What will the study involve?

This study mainly involves the assessment of the mouth opening after radiotherapy. Your mouth opening will be assessed before and after radiotherapy for up to 3 months. Participants will be taught simple jaw exercise instructions, while another group will have jaw exercises using a wooden spatula.

How will the mouth opening assessment done?

The mouth opening assessment will be done by using a measurement device that will measure your mouth opening, and the measurement will be recorded. This measurement will be done before radiotherapy, after 10th week and lastly 20th week after radiotherapy.

Risks

This research project intends to assess any measures that can prevent limitations in mouth-opening following head and neck radiotherapy. There are no risks exposed to the participant caused by the mouth opening exercise during mouth opening measurement. If there is worsening or no improvement post-intervention, the patient will be offered further treatment.

Benefits

If it is effective, you might benefit from the exercise in preventing the mouth opening limitation. The research findings will also help in regards to the management of future patients undergoing similar treatment.

Do you have to take part?

Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form." You will be given a copy of the form and this Information Sheet. Your PIS Version 2.0 dated 1 Feb 2021

treatment is unaffected if you decide not to participate in this study. Should you choose not to participate when the investigation is ongoing, you can still withdraw from the study without penalty. Your data will not be used and will be discarded. The researcher may also remove you from the study for various reasons. In this event, you will not be penalized or lose your rights as a patient.

Data & Confidentiality:

The data from this study will be made into a report which may be published. Access to the data is only by the research team and the Research Ethics Committee (REC) UKM. The data will be reported collectively with no reference to an individual. Hence your identity will be kept confidential.

Payment and compensation:

You do not have to pay, nor will you be. You do have to pay for the usual treatment charges.

Whom can you ask about the study?

If you have any questions, you can direct them to the research team. You can also contact the Research Ethics Committee (REC) UKM for clarifications.

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