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Comparison of organs at risk and target volumes using MRI and CT scan in head and neck malignancy radiation treatment planning

Submission date
26/08/2021

Recruitment status
No longer recruiting

Registration date
07/04/2022

Overall study status
Completed

Last Edited
11/05/2022

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Malignancies (cancers) of the head and neck are a significant health problem in India comprising about one-third of all cancer cases. Males are affected significantly more than females, with a ratio ranging from 2:1 to 4:1. The increase in the use of tobacco over the last few decades has led to an increase in tobacco-related malignancies in India. With 77,000 cases diagnosed per year, head and neck malignancy is the second most common malignancy in the Indian population. The major risk factors associated with malignancies of the head and neck are smoking, alcohol, betel quid, and infection by the human papillomavirus and Epstein-Barr virus. Cigarette smoking and alcohol consumption certainly have a synergistic effect leading to the development of head and neck cancers. The chewing of betel quid (also known as 'pan') has been associated with mouth cancer.
The two main techniques of radiation treatment are external beam radiation therapy (EBRT), where the radiation is delivered to the tumour from an external source outside the body, and brachytherapy, where the radiation is delivered by a radioactive source placed inside the body using radioactive implants. Techniques of EBRT include the following. 2DRT relies on 2D images from conventional X-rays which delineate structures based on bony anatomy. 3DCRT is planned using 3D images, such as CT or MRI, and the radiation beams are shaped (conformed) to the tumour. IMRT is intensity-modulated radiotherapy where the intensity of the beams can be varied in order to shape the dose very precisely to the tumour. Stereotactic radiation therapy conforms extremely precisely to the tumour and gives very high accuracy. Stereotactic radiation therapy can be used to treat brain, early-stage lung, pancreatic, and prostate tumours. IGRT (image-guided radiotherapy) refines the delivery of radiation by image-based target localization to allow proper patient positioning so that accurate treatment delivery can be ensured with minimal normal tissue toxicity.
With the use of techniques like IMRT, it has now become possible to deliver highly precise doses of radiation to the tumour; accurate delineation of tumour volume is hence highly crucial in this technique. Traditionally the Gross Tumour Volume (GTV) is defined as evident disease and nowadays, efforts to improve GTV delineation have been helped considerably with the evolution of new imaging methods. CT has been used conventionally as the imaging method for target volume delineation. MRI has better soft-tissue contrast and lesser artefacts. Other functional

imaging modalities like PET-CT and DW-MRI have also been studied in recent times. The best choice of imaging method to accurately define the GTV in patients with locally advanced head and neck squamous cell carcinoma is still debatable. The aim of this study is to compare MRI and CT scan based delineation of target volume and Organs At Risk (OARs) in head and neck cancers.

Who can participate?
Newly diagnosed biopsy-proven head and neck cancer patients aged over 18 years with a good performance status and a normal kidney function test

What does the study involve?
Along with radiation treatment planning, CT scans and planning MRI scans are taken. The simulation CT scan is fused with the planning MRI scan. The primary tumour, node, and organs at risk are contoured separately with CT and MRI. The researchers compare the MRI and CT scan-based delineation of gross tumour volume and organs at risk.

What are the possible benefits and risks of participating?
Possible benefits may include better local control and lesser normal tissue radiation toxicity as MRI is used in addition to a CT scan and this may lead to better delineation, but this was not a part of the study and hence was not analysed clinically. There are no possible risks of participating in the study

Where is the study run from?
All India Institute of Medical Sciences (India)

When is the study starting and how long is it expected to run for?
January 2020 to September 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Lekshmi R
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparison of magnetic resonance imaging and CT scan based delineation of target volumes and organs at risk in the radiation treatment planning of head and neck malignancies

Study objectives
To compare the gross tumour volume and delineation of organs at risk with CT and MRI scans in radiation treatment planning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2020, Institutional Ethics Committee (All India Institute of Medical Sciences, Rishikesh, 249203, India; +91 (0)135 2462940; iec@aiimsrishikesh.edu.in), ref: AIIMS/IEC/20/604

Study design
Single-center cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied
Newly diagnosed biopsy-proven head and neck malignancy

Interventions
Pre-treatment staging and workup:
Detailed clinical history and physical examination, biopsy from the lesion, complete haemogram, liver function test, kidney function test, chest x-ray, staging as per American Joint Committee on Cancer (AJCC) Cancer Staging Eighth Edition, dental evaluation, and assessment of nutritional status.

Immobilization and CT simulation:
Patients will be immobilized in a supine position with hands on the side with a 5 clamp thermoplastic head and neck cast and neck rest.

CT scan for RT planning will be done on a GE Optima machine with 2.5 mm slice thickness.

Radiotherapy (RT) planning MRI scan will be done on a GE Discovery 3T system and axial post-contrast T1-weighted and axial fat saturated T2-weighted sequences will be acquired in treatment position with 1 mm slice thickness using customised head and neck thermoplastic cast and neck rest for positional replication and maintenance of neck-chin distance.

Fusion and registration:
Rigid image registration of planning CT scan image will be done with MRI and fusion accuracy will be ensured by manual adjustment between the CT dataset and T1-weighted MR dataset.

Target and OAR delineation:
GTVp and GTVn will then be delineated on CT and MRI images based on the site and the stage of the disease by one observer.

Organs at Risk (OARs):
Organs at risk, including the spinal cord, brain stem, parotid gland, submandibular salivary gland, pharyngeal constrictor muscles, will be delineated on CT and MRI.

Volumetric Analysis:
The GTV defined by CT (GTV-CT) will be compared with the GTV acquired by MRI (GTV-MRI) and volumetric evaluation will be performed using the Conformity Index, DICE Similarity Coefficient (DSC), Sensitivity Index and Inclusion Index.

There is no follow up of patients.

Intervention Type
Procedure/Surgery

Primary outcome measure
Concordance in CT and MRI contouring of target volumes and organs at risk, measured using the Dice Similarity Coeffcient, Conformity Index, Sensitivity Index, and Inclusion Index, calculated at the time of contouring

Secondary outcome measures

There are no secondary outcome measures

Overall study start date
01/01/2020

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Newly diagnosed biopsy-proven head and neck cancer
2. Age over 18 years
3. Eastern Co-operative Oncology Group (ECOG) performance status of 0- 2
4. Normal kidney function test

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
54

Total final enrolment
54

Key exclusion criteria
1. Poor performance status of ECOG 3-4
2. Deranged serum creatinine and blood urea
3. Presence of metal elements in patient’s body that are MRI incompatible
4. Allergy to CT or MRI contrast
5. Second primary/recurrent head and neck cancer
6. Patients who have undergone tracheostomy

Date of first enrolment
02/01/2020

Date of final enrolment
30/01/2021

Locations

Countries of recruitment
India

Study participating centre
All India Institute of Medical Sciences, Rishikesh
Department of Radiation Oncology
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India
249203

Sponsor information

Organisation
All India Institute of Medical Sciences, Rishikesh

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Sponsor type
Hospital/treatment centre

Website
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
25/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Lekshmi R (luckylekshmi@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			17/01/2022	No	No