# Title : PET MRI as a Staging Tool for Head and Neck Cancer

ClinicalTrials.gov Identifier: NCT04750434

**Sponsor:**

Hoag Memorial Hospital Presbyterian

**Information provided by (Responsible Party):**

Hoag Memorial Hospital Presbyterian

**Study Description**

Brief Summary:

To explore the use of PET/MRI in the staging and pretreatment evaluation of patients with head and neck cancer and to compare this modality to standard PET/CT imaging.

Condition or Disease:

Head **Cancer**

Neck **Cancer**

Detailed Description:

This study is a prospective clinical study whereby an emerging technology, PET/MRI will be compared to a more standard imaging modality, PET/CT, using newly diagnosed head and neck cancer patients as subjects. PET/MRI will also be used in this study to explore the merits of this new technology in determining extent of disease, functional impact, and potential treatment outcome.

In this study, subjects suitable for enrollment will be identified by the investigators involved in the study. These subjects will be identified through contact with these investigators and referred for enrollment per protocol. This protocol will include determining enrollment suitability based on inclusion and exclusion criteria. Once accepted as a candidate for the study, the newly diagnosed head and neck cancer patients will undergo both PET/CT and PET/MRI imaging within one week of each other. These studies will then be reviewed by a radiologist specializing in Head and Neck radiology familiar with PET imaging. The studies will be compared for any imaging differences. The imaging findings will then be correlated with pathological findings after surgery to determine if there are any consistent findings that correlate with adverse pathological findings, if found.

The specific imaging data points to be determined by a radiologist will be tumor and metastatic disease size, SUV uptake, specific anatomic structures involved with tumor, imaging irregularities and characteristics of those imaging irregularities of the involved structures locally and regionally (if present), imaging characteristics of the different phases of MRI (T1, T2, etc.), and any other notable imaging characteristic.

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| Study Type  : | Observational |
| Estimated Enrollment  : | 20 participants |
| Observational Model: | Case-Crossover |
| Time Perspective: | Prospective |
| Official Title: | PET MRI as a Staging Tool for Head and Neck **Cancer** |
| Actual Study Start Date  : | March 3, 2020 |
| Estimated Primary Completion Date  : | August 2023 |
| Estimated Study Completion Date  : | December 2023 |

**Outcome Measures**

**Outcome Measures**

Primary Outcome Measures  :

1. PET MRI as a Staging Tool for Head and Neck Cancer [ Time Frame: 18 months ]

Outcomes from this study will include a comparison of PET/MRI with PET/CT directly in a series of patients where surgical pathology specimens are available for correlation.

**Eligibility Criteria**

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| Ages Eligible for Study: | 18 Years and older   (Adult, Older Adult) |
| Sexes Eligible for Study: | All |
| Accepts Healthy Volunteers: | No |
| Sampling Method: | Probability Sample |

**Study Population**

All patients who are referred to Hoag for imaging services related to Head and Neck cancer will be recruited.

**Criteria**

Inclusion Criteria:

* Active head and neck cancer that require PET/CT regardless of the point of treatment
* TNM staging I or II

Exclusion Criteria:

* Patients whose primary treatment option is chemotherapy or radiation therapy (not surgical)
* Implanted pacemakers
* Intracranial aneurysm clips
* Cochlear implants
* Certain prosthetic devices
* Implanted drug infusion pumps
* Neurostimulators
* Bone-growth stimulators
* Certain intrauterine contraceptive devices; or
* Any other type of iron-based metal implants.
* MRI should not also be used on persons with the presence of internal metallic objects such as bullets or shrapnel, as well as surgical clips, pins, plates, screws, metal sutures, or wire mesh.
* Subject with breast tissue expanders.

**Locations**

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| **United States, California** | |
| Hoag Memorial Hospital Presbyterian | **Recruiting** |
| Newport Beach, California, United States, 92663 | |
| Contact: Leila Andres       [leila.andres@hoag.org](mailto:leila.andres%40hoag.org?subject=NCT04750434,%20161-19-HC,%20PET%20MRI%20as%20a%20Staging%20Tool%20for%20Head%20and%20Neck%20Cancer) | |
| Principal Investigator: Timothy Kelley, MD | |

**Sponsors and Collaborators**

Hoag Memorial Hospital Presbyterian