Background

Breast cancer (BC) staging is essential to planning the most appropriate treatment pathway. Currently, BC management has become more tailored to the tumor and patient’s characteristics. However, BC imaging shows varying performance according to tumor subtypes. In particular, routine imaging may pose some challenges when evaluating luminal A (LumA) and lobular BC (Lob). LumA, due to low grade and proliferation index (<20%) shows lower sensitivity on auxiliary US, reduced MRI enhancement, and low FDG-avidity on PET. Similarly, Lob, due to its peculiar single-cell growth pattern, exhibits inferior sensitivity on auxiliary MRI and FDG-avidity. LumA and Lob account for >90% of all BCs. Despite their favorable prognosis, metastases and recurrences still occur; this translates into a higher absolute number of events than in other subtypes. As a result, a concrete risk of disease underestimation and undertreatment exists. Two ongoing studies on FES-PET/MRI imaging in our institution have already demonstrated that its sensitivity also decreases in LumA and Lob. Based on these premises, our hypothesis states that by combining the advantages of hybrid PET/MRI with the high accuracy of 18F-fluorodeoxyglucose (FDG), a radiolabeled form of estrone binding to functionally active ER, we could obtain a reliable, non-invasive, operator-independent, one-stage imaging method for staging LumA and ER-positive Lob.

Methods

This study is a prospective, observational, multicenter study (Fig. 1) where patients with LumA and ER-positive Lob will be enrolled in four cohorts undergoing: A) primary surgery; B) induction endocrine therapy; C) neoadjuvant chemotheraphy, and D) systemic therapy for metastatic disease. FES PET/MRI examinations will be performed at baseline for local and systemic staging in all cohorts and a second exam after systemic therapy in cohorts C-D. Correlations between the FES PET/MRI parameters and pathology, gene expression, and FDG PET parameters, when available, will be investigated.

Results

18F-FES PET/MRI for tailoring treatment of luminal A and lobular breast cancer: a phase I/II prospective cohort study evaluating the feasibility of FES PET/MRI in axillary staging compared with (FESTA trial)

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Objective

The primary objectives of the FESTA trial are to evaluate the feasibility of FES PET/MRI in axillary staging compared with FDG PET/MRI, and to determine the performance of FES PET/MRI in axillary staging compared with standard imaging.

Design

This is a single-center, prospective cohort study to evaluate the feasibility of FES PET/MRI in axillary staging compared with FDG PET/MRI, and to determine the performance of FES PET/MRI in axillary staging compared with standard imaging.

Participants

Patients with histologically confirmed operable breast cancer, aged ≥18 years, with a Ki-67 of ≤14%, will be consecutively recruited at the Department of Radiation Oncology, IRCCS San Raffaele Scientific Institute, via Olgettina 60, 20132 Milan, Italy, or the Department of Radiation Oncology, IRCCS San Raffaele Scientific Institute, via Olgettina 60, 20132 Milan, Italy. The primary endpoint of the study is the proportion of patients correctly staged with FES PET/MRI compared with standard imaging.

Interventions

FES PET/MRI + FDG PET at baseline and first month after treatment initiation.

Outcomes

The primary outcome is the proportion of patients correctly staged with FES PET/MRI compared with standard imaging. Secondary outcomes include the proportion of patients correctly staged with FES PET/MRI compared with FDG PET/MRI, the proportion of patients correctly staged with FES PET/MRI compared with standard imaging, and the proportion of patients correctly staged with FES PET/MRI compared with FDG PET/MRI.

Statistics

The primary analysis in cohort A will test the sensitivity of the FES PET/MRI in detecting macrometastatic axillary nodes (Fig. 1). The test will be performed using the Wilcoxon signed-rank test for paired data. The Wilcoxon signed-rank test will be used for paired data. The primary analysis in cohort B will test the association between the change in the FES-SO change from pre-treatment to post-treatment and the Ki-67 change from core biopsy to post-treatment. The significance level will be set at 0.05.

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