CERIANNA™
(FLUOROESTRADIOL F 18) INJECTION

A molecular imaging diagnostic PET agent for recurrent or metastatic ER+ breast cancer patients

Clear diagnosis, more confident treatment

Dr. Gary Ulaner, Hoag Family Cancer Institute.

GE HealthCare

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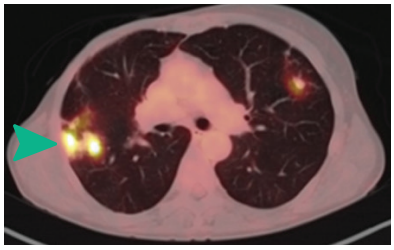
High diagnostic accuracy[1]

Patient is a female in her 50s with history of invasive lobular carcinoma. She presented with a suspected recurrence and underwent FDG PET/CT and Cerianna (FES) PET/CT as part of a clinical trial. FDG PET/CT showed avid lung nodules which were suspicious for malignancy. The lung nodule was subsequently biopsied but found to represent benign granulomatous inflammation and thus a false positive on FDG PET/CT.[2]

Cerianna (FES) PET/CT demonstrated no avidity in the biopsy-proven benign granulomatous lung nodules, thus true negative on Cerianna. Cerianna-avid lymph nodes, gastric, and osseous foci were suspicious for ER+ malignancy. Osseous focus was subsequently biopsied and proved to be an osseous metastasis and thus true positive on Cerianna.[2]

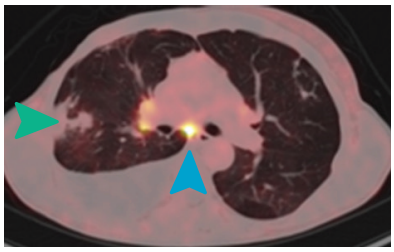
FDG PET/CT: Maximum intensity projection image

FDG–avid lung nodules

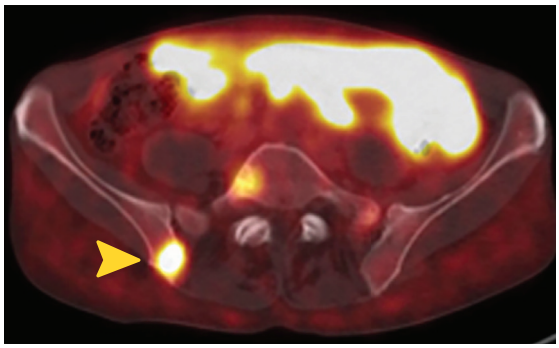


Cerianna (FES) PET/CT: Maximum intensity projection image

Cerianna (FES) negative lung nodules, positive lymph node



True positive osseous lesion on Cerianna (FES) PET/CT



Key takeaways

- FDG PET/CT demonstrated a false positive finding in the lung confirmed by biopsy showing benign granulomatous disease and negative Cerianna (FES) PET/CT. Cerianna (FES) PET/CT demonstrated true positive finding in the bone confirmed by biopsy showing osseous metastasis.
- ***Cerianna (FES) binds to the estrogen receptor with high affinity.***[3]

Images courtesy of Dr. Gary Ulaner, JAMA Netw Open.

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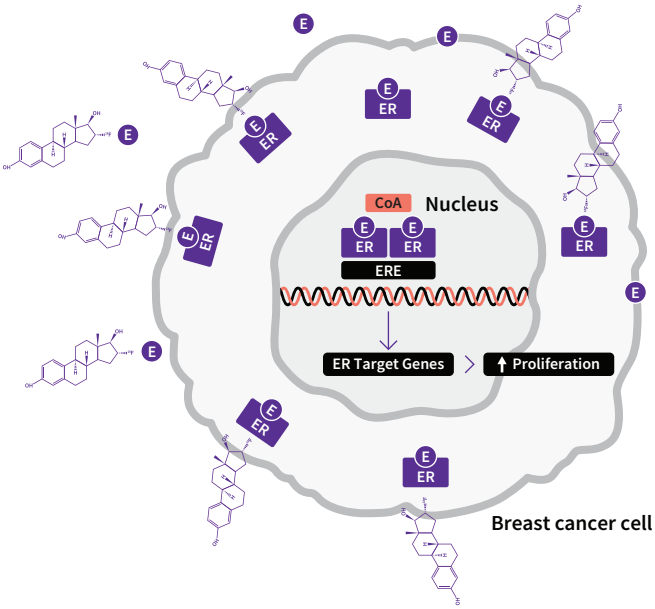
Cerianna mechanism of action

Cerianna, F18 fluoroestradiol (FES), is a radiolabeled estrogen analog that is used with positron emission tomography (PET) imaging to determine the ER status of recurrent and metastatic breast cancer tumors.[4] Cerianna binds to estrogen receptors allowing for the visualization of ER expression in vivo.[5]

Uptake of Cerianna is not specific for breast cancer and may occur in a variety of ER-positive tumors (uterus and ovaries).



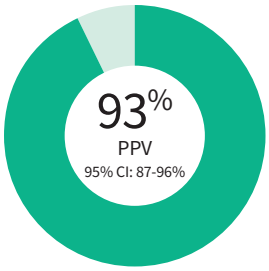
FDG mechanism of action

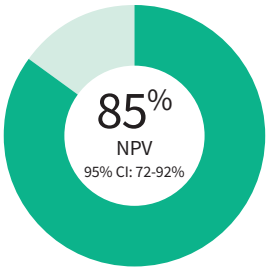
FDG PET is often used as a diagnostic tool for staging and measuring treatment response. It is an effective approach for assessing highly metabolic breast tumors due to the glucose consumption by the cancer cell. FDG PET does have limitations as its uptake varies with molecular and histological tumor subtypes.[6] **FDG may not be effective for detecting low metabolically active breast cancer lesions.**[7] This is a significant consideration when it comes to ER+ breast cancers.

Diagnostic accuracy

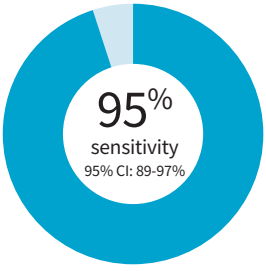
The IMPACT-MBC study*

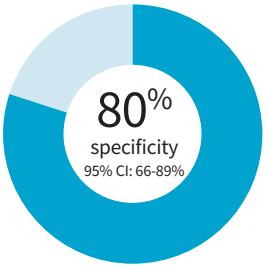
Studied the diagnostic performance of qualitative FES PET in predicting ER expression in biopsied metastases in a cohort of newly diagnosed, non rapidly progressing patients with MBC. Based on the findings of the impact study, FES PET demonstrated a positive predictive value (PPV) of 93% (87-96) and a negative predictive value (NPV) of 85% (72-92) in predicting ER immunohistochemical (IHC) status.[1]





Concordance between F18 FES imaging and IHC





*The F18 FES administered in this study was not equivalent to the FDA-approved formulation of Cerianna.

*University Medical Center Groningen was the sponsor for this study.

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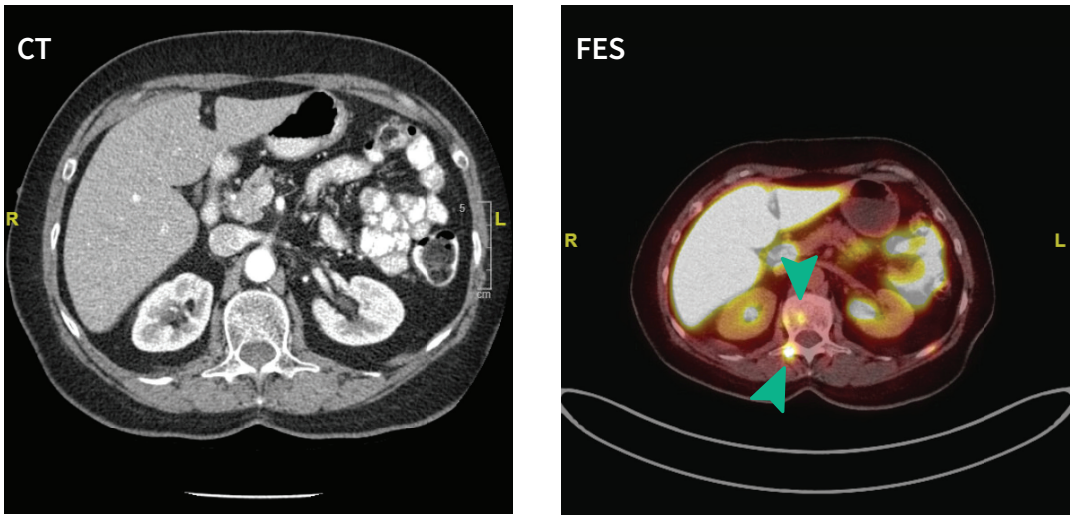
Closing the gap in diagnostic dilemmas for recurrent or metastatic ER+ breast cancer patients

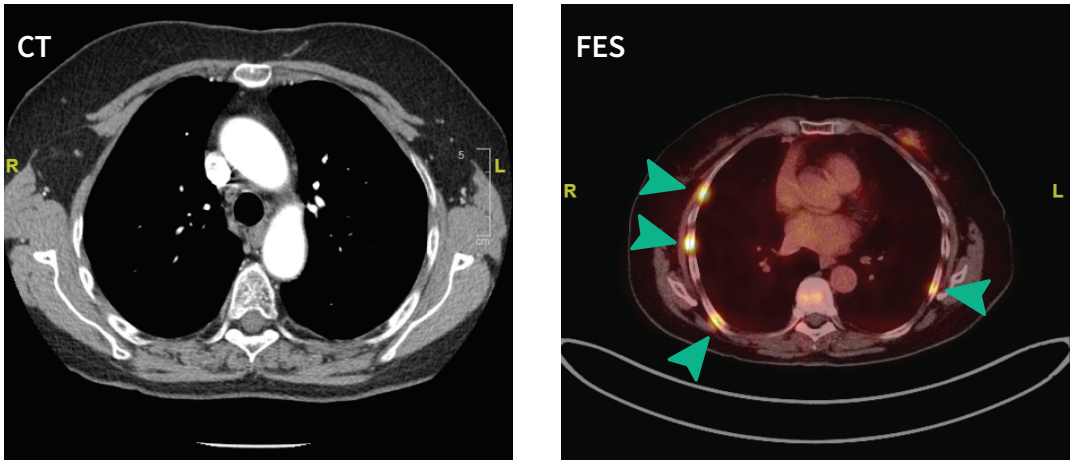
68-year-old female presented with a left breast cancer, ER+/PR+/HER2-. Breast MRI was completed for surgical planning and revealed the left breast cancer as well as an incidental 1.3 cm right paramedian sternal mass and 2 questionable right rib lesions. CT chest/abdomen/pelvis was negative. Bone scan was negative for osseous metastases and showed a healed left 10th rib fracture.

Cerianna (FES) PET was ordered to help better understand ER+ disease extent given multiple equivocal findings on other imaging modalities.

Vertebral lesions



Rib lesions



Key takeaways

- Cerianna (FES) PET demonstrated over 90 metastatic ER+ osseous lesions. The patient did not proceed with surgery with new stage IV diagnosis and was started on systemic therapy.
- ***Cerianna (FES) PET helped guide the change in management for this ER+ breast cancer patient.***

Images courtesy of Dr. Valerie Gorman, Baylor Scott and White Health.

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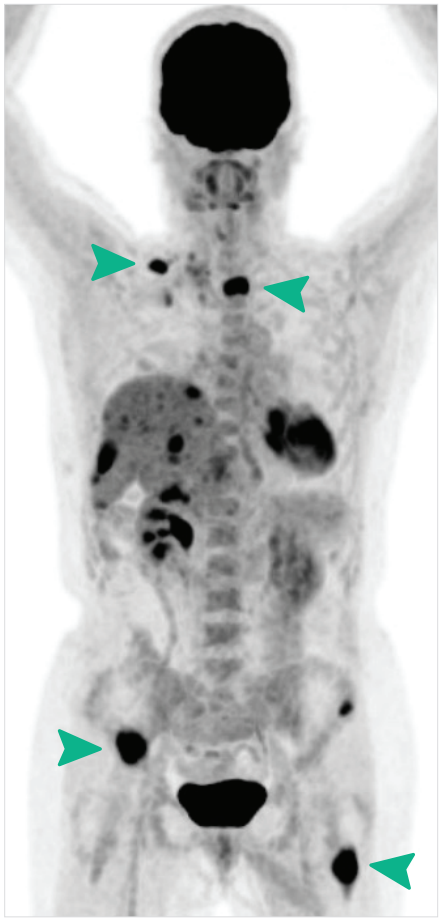
Cerianna is reshaping the diagnostic landscape for ER+ breast cancer patients

58-year-old female presented with de novo metastatic breast cancer. Pathology showed an invasive ductal carcinoma, ER 3+/PR 3+/HER2 1+. She was treated with letrozole and palbociclib. She was being monitored with FDG PET/CT which demonstrated increasing bone and liver metastases.

Cerianna (FES) PET/CT was ordered given progression of disease on first line endocrine therapy to understand if her disease was still hormone dependent.

FDG PET



Cerianna (FES) PET

Key takeaways

- Cerianna (FES) PET findings suggested lack of functional ER, thereby impacting the next line of treatment away from ET to a chemotherapy based regimen.
- ***Cerianna's binding ability to the estrogen receptor helped lead to a clearer diagnosis, resulting in a more tailored therapy decision for the patient.***
- Cerianna (FES) PET may miss liver metastases due to high background liver uptake.

Images courtesy of Dr. Gary Ulaner, Hoag Family Cancer Institute.

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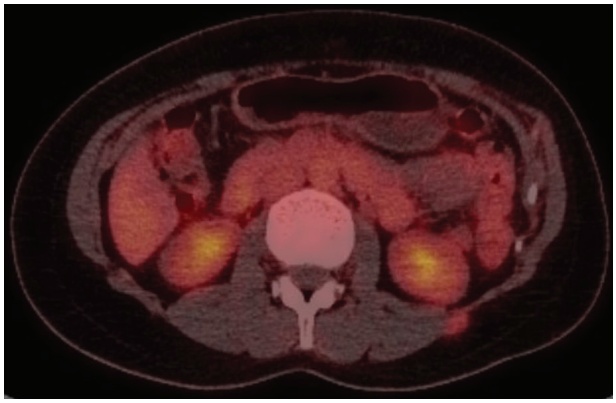
Cerianna may help you treat ER+ patients with more confidence

Tailoring treatment plans for patients with ILC

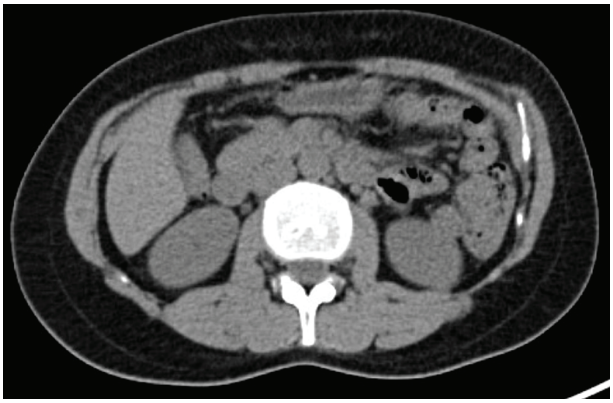
Patient with a history of early-stage invasive lobular carcinoma (ILC), ER+. She presented 5 years later with a new left chest wall recurrence. She underwent FDG PET/CT and Cerianna (FES) PET/CT to evaluate disease extent given recurrence of her breast cancer. FDG PET/CT showed the left chest wall recurrence and a few patchy right lung opacities, probably benign/infectious. Biopsy of the right lung opacity revealed benign granulomatous disease.

Cerianna (FES) PET/CT showed avid left chest wall and left subcutaneous back lesions all consistent with ER+ malignancy. The soft tissue nodule of the left lower back was subsequently biopsied and showed involvement by metastatic carcinoma ER 3+ 90%, PR -, HER2 low.

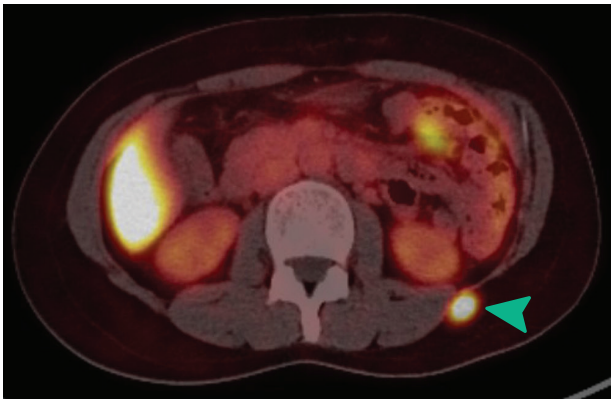
FDG PET/CT: left back



CT: left back



Cerianna (FES) PET/CT: left back



It is known that 18F-FDG uptake is generally low in low-grade tumors, estrogen receptor (ER)– positive disease, and the lobular histologic type. This can lead to missed lesions and inconclusive staging.[8]

Key takeaways

- Patient was upstaged to stage IV disease and treated with systemic therapy.
- *Cerianna may help provide a clearer diagnosis leading to a more confident treatment plan.*

Images courtesy of Dr. Gary Ulaner, Hoag Family Cancer Institute.

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Guideline recommendations for using FES PET/CT

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

FES PET/CT is included as an imaging option for systemic staging of ER+ recurrent / stage IV (M1) disease in the NCCN Guidelines® for Breast Cancer

Recurrent/stage IV (M1) disease

Clinical stage

Stage IV (M1) or recurrent ›

Workup

History and physical exam

Discuss goals of therapy, adopt shared decision-making, and document course of care

CBC

Comprehensive metabolic panel, including liver function tests and alkaline phosphatase

Imaging for systemic staging:

- Chest diagnostics CT ± contrast
- Abdomen ± pelvis diagnostic CT with contrast or MRI with contrast
- Brain MRI with contrast if suspicious CNS symptoms
- Spine MRI with contrast if back pain or symptoms of cord compression
- Bone scan or sodium fluoride PET/CT (NCCN Category 2B)
- Useful in certain circumstances: FDG PET/CT **(consider FES PET/CT for ER-positive disease and lobular histology)**
- X-rays of symptomatic bones and long and weight-bearing bones abnormal on bone scan

Biomarker testing

- Biopsy of at least first recurrence of disease (consider re-biopsy if progression)
- Evaluation of ER/PR and HER2 status
- Comprehensive germline and somatic profiling to identify candidates for targeted therapies

Genetic counseling if patient is at risk for hereditary breast cancer

Assess for distress

NCCN Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.

SNMMI appropriate use criteria

4 scenarios for appropriate use criteria

Assessing ER status in lesions that are difficult to biopsy, or when biopsy is nondiagnostic

After progression of metastatic disease, for considering second line of endocrine therapy

At initial diagnosis of metastatic disease, for considering endocrine therapy

Detecting ER status when other imaging tests are equivocal or suggestive

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Important safety information

Indications and usage

CERIANNA is indicated for use with positron emission tomography (PET) imaging for the detection of estrogen receptor (ER)-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer.

Limitations of use

Tissue biopsy should be used to confirm recurrence of breast cancer and to verify ER status by pathology. CERIANNA is not useful for imaging other receptors, such as human epidermal growth factor receptor 2 (HER2) and the progesterone receptor (PR).

Contraindications

None

Warnings and precautions

Risk of misdiagnosis

Inadequate tumor characterization and other ER-positive pathology

Breast cancer may be heterogeneous within patients and across time. CERIANNA images ER and is not useful for imaging other receptors such as HER2 and PR. The uptake of fluoroestradiol F 18 is not specific for breast cancer and may occur in a variety of ER-positive tumors that arise outside of the breast, including from the uterus and ovaries. Do not use CERIANNA in lieu of biopsy when biopsy is indicated in patients with recurrent or metastatic breast cancer.

False negative CERIANNA scan

A negative CERIANNA scan does not rule out ER-positive breast cancer. Pathology or clinical characteristics that suggest a patient may benefit from systemic hormone therapy should take precedence over a discordant negative CERIANNA scan.

Radiation risks

Diagnostic radiopharmaceuticals, including CERIANNA, expose patients to radiation. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe drug handling and patient preparation procedures (including adequate hydration and voiding) to protect patients and health care providers from unintentional radiation exposure.

Pregnancy status

Assessment of pregnancy status is recommended in females of reproductive potential before administering CERIANNA.

Adverse reactions

In Clinical Trials (n=1207) the most common adverse reactions seen occurred at a rate <1% were injection-site pain and dysgeusia.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2 then option 1) or by email at GPV.drugsafety@gehealthcare.com or FDA at 800 FDA 1088 or www.fda.gov/medwatch

The full Prescribing Information for Cerianna can be found **here**.

Use in specific populations

Pregnancy

Risk summary

- All radiopharmaceuticals, including CERIANNA, have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of radiation dose. Advise a pregnant woman of the potential risks of fetal exposure to radiation from administration of CERIANNA.
- There are no available data on CERIANNA use in pregnant women. No animal reproduction studies using fluoroestradiol F 18 have been conducted to evaluate its effect on female reproduction and embryo-fetal development.
- The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Lactation

Risk summary

There are no data on the presence of fluoroestradiol F 18 in human milk, or its effects on the breastfed infant or milk production. Lactation studies have not been conducted in animals. Advise a lactating woman to avoid breastfeeding for 4 hours after CERIANNA administration in order to minimize radiation exposure to a breastfed infant.

Pediatric use

The safety and effectiveness of CERIANNA in pediatric patients have not been established.

Geriatric Use

Clinical studies of fluoroestradiol F 18 injection did not reveal any difference in pharmacokinetics or biodistribution in patients aged 65 and over.

Drug interactions

Systemic endocrine therapies that bind to ER

- Drugs that bind to the ER, including SERMs and SERDs, may compete with the binding of fluoroestradiol F18 and may reduce detection of ER-positive lesions with CERIANNA.
- Before administration of CERIANNA, discontinue drugs that bind to the ER, such as SERMs and SERDs, for at least 5 biological half-lives: (e.g. elacestrant for 11 days, tamoxifen for 8 weeks and fulvestrant for 28 weeks).

Acronym definitions

ER, estrogen receptor; **ER+**, estrogen receptor-positive; **FDG,** fluorodeoxyglucose; **FES,** fluoroestradiol; **PR**, progesterone receptor; **PR+**, progesterone receptor-positive; **PR-**, progesterone receptor-negative; **HER2**, human epidermal growth factor receptor two; **HER2-**, human epidermal growth factor receptor two negative; **PET**, positron emission tomography; **CT**, computed tomography; **MBC**, metastatic breast cancer; **MRI**, magnetic resonance imaging; **ET**, endocrine therapy; **NCCN**, National Comprehensive Cancer Network; **M1**, metastasis one; **CBC**, complete blood count; **CNS**, central nervous system; **SNMMI**, Society of Nuclear Medicine and Molecular Imaging

References

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