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PET2015UZ: Prognostic value of pre-treatment 18FDG-PET in operable breast cancer

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Vincent Vinh-Hung¹, Hendrik Everaert², Mark De Ridder²

¹CHU Martinique; ²UZ Brussel



Vincent Vinh-Hung

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Protocol status: Working

We use this protocol and it's working

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Keywords: 18F-Fluoro-deoxyglucose, Breast cancer, Surgery, Survival, Prognostic value, Positron emission tomography,

Abstract

This retrospective-observational study hypothesizes that preoperative 18FDG-PET for breast cancer has significant prognostic value for the prediction of survival. Data from patients who had breast surgery and had a preoperative FDG-PET examination at the UZ Brussel in 2002-2008 and in 2009-2015 will be analyzed without restriction on age or sex. Data collection for the cohort 2002-2008 has been finalized and will be shared on Mendeley (Reserved DOI: 10.17632/sfvtmrd8z9.1). Data for the cohort 2009-2015 will be collected by end of 2020.

Detailed and referred to in:

Breast cancer preoperative 18FDG-PET, overall survival prognostic separation compared with the lymph node ratio.

Vinh-Hung V, Everaert H, Gorobets O, Van Parijs H, Verfaillie G, Vanhoeij M, Storme G, Fontaine C, Lamote J, Perrin J, Farid K, Nguyen NP, Verschraegen C, De Ridder M.

Breast Cancer. 2021 Jul;28(4):956-968. doi: 10.1007/s12282-021-01234-z

PMID: 33689151

<https://link.springer.com/article/10.1007%2Fs12282-021-01234-z>

Is there a utility of [18F]FDG-PET before surgery in breast cancer? A 15-years overall survival analysis.

Perrin, Farid K, Van Parijs H, Gorobets O, Vinh-Hung V, Nguyen NP, Djassemi N, De Ridder M, Everaert H.

World J Clin Oncol. Pending.

Study registration:

<https://www.isrctn.com/ISRCTN17962845>

Attachments



ISRCTN17962845_Proto.

981KB

Safety warnings



Before pooling any data:

Investigator ascertains unique study number to patients.

Lock the study's master list in a password protected file.

Delete all identification information (name, medical file number) in the file retained for analyses.

Before start

Contact Vincent: vh@onco.be or anhxang@gmail.com for data layout.



Review medical records

1 **Check inclusion criteria**

- 1.1 Participating center
- 1.2 Period of diagnosis: 2002-2015
- 1.3 Primary breast cancer
- 1.4 Histologically confirmed
- 1.5 Operable - curative surgery
- 1.6 Pre-treatment FDG-PET or PET/CT

2 **Check exclusion**

- 2.1 Previous history of cancer
- 2.2 The breast tumor is a primary sarcoma
- 2.3 Surgery was done for palliation, for symptom control
- 2.4 No histopathological confirmation of cancer
- 2.5 Non-invasive carcinoma



2.6 Metastatic disease demonstrated by imaging modes other than FDG-PET

Data collection

3 **Clinical-pathological characteristics**

3.1 Age at diagnosis

3.2 Sex

3.3 Disease presentation (screening or symptomatic)

3.4 Laboratory markers

3.5 Source material of initial pathology (cytological/biopsy/excision)

3.6 Histological tumor type

3.7 Pathological grade

3.8 Hormone receptor status

3.9 Her2/neu status

3.10 Lymphovascular invasion



- 3.11 Breast inflammation
- 3.12 Breast skin invasion
- 3.13 Tumor laterality
- 3.14 Tumor location
- 3.15 Clinical tumor size
- 3.16 Pathological tumor size
- 3.17 Number of examined axillary lymph nodes
- 3.18 Number of involved axillary lymph nodes
- 3.19 Neoadjuvant therapy
- 3.20 Type of surgery
- 3.21 Adjuvant chemotherapy
- 3.22 Adjuvant hormone therapy
- 3.23 Adjuvant radiation therapy
- 4 FDG-PET characteristics**

4.1 Type of exam (PET only / PET-CT)

4.2 Pattern of PET positivity (visual pathologically increased uptake):
breast,
axillary-supraclavicular region,
internal mammary nodes,
distant.

4.3 Standard uptake value (SUV) based on regions of interests:
SUVmax global (whole body).
SUVmax within breast, right and left.
SUVmax axillary-supraclavicular region, right and left.
SUVmax internal mammary nodes.

5 **Outcomes**

5.1 Local (in-breast) recurrence

5.2 Regional (axillary, supraclavicular, internal mammary nodes) recurrence

5.3 New primary tumor (breast/non-breast)

5.4 Censor status at last follow-up (alive/died)

5.5 Disease status at last follow-up (NED, no evidence of disease/WD, with cancer)

5.6 Cause of death

Data analyses

6 **Statistics**

6.1 **Descriptive statistics.**

Clinical- pathological characteristics and patterns of PET uptake.

6.2 **Relationships:**

between the characteristics and the patterns of PET uptake.

6.3 **Disease-free survival (DFS):**

event defined as any local-regional or distant recurrence, new primary tumor, or death from any cause.

6.4 **Overall survival (OS):**

event defined as death from any cause.

6.5 **Explorative analyses:**

Multivariate Cox regression analyses of DFS and OS.

Evaluate the prognostic value of patterns of PET positivity using the Akaike information criterion (AIC) and using indexes of the proportion of variation explained by covariates.

6.6 **Handling of missing data:**

If missing in <10% of the cases, impute using multivariate imputation by chained equations. If missing in 10% or more, consider separate analyses.