ADDED VALUE OF 18FDG-PET-CT IN THE DIAGNOSIS OF INVASIVE FUNGAL INFECTIONS IN NEUTROPENIC PATIENTS

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Objective: The primary objective of this pilot study is to compare FDG-PET-CT with HR-CT alone and to HR-CT and galactomannan test together for early diagnosing IFIs in neutropenic patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON35827

Source
ToetsingOnline

Brief title
Value of FDG-PET-CT in fungal infections in neutropenic patients

Condition

- Haematological disorders NEC
- Fungal infectious disorders

Synonym
Invasive aspergillosis; fungal infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diagnosis, FDG-PET-CT, Fungal infection, Neutreopenia

Outcome measures

Primary outcome

Has FDG-PET-CT additional value as imaging modality compared to the HR-CT thorax? Are their specific imaging characteristics found on FDG-PET-CT in relation to the 3 different described lesions found by HR-CT? Can FDG-PET-CT also provide information about the extension of the known lesions, i.e. is the halo sign on HR-CT involved in the infectious process or is it a sign of decreased perfusion due to infarction?

* Can FDG-PET-CT detect enlarged and/or positive lymph nodes and what is the meaning of these lymph nodes in relation to prognosis or GM detection?

* Is FDG-PET-CT able to find additional infectious lesions that are not visible on HR-CT of the thorax? Can FDG-PET-CT detect smaller lesions than HR-CT by its metabolic positivity and is there a relation between the total amount of metabolic positivity of lesions (mean SUV times area of positivity) and galactomannan positivity, which is a parameter of activity and/or invasiveness of aspergillosis?

* Is FDG-PET-CT able to find additional infectious lesions that are not visible on HR-CT of the thorax because they are found outside the thorax? Sometimes IFI are found in the sinussen or gut or brain or combinations of these localisations.

Secondary outcome

Not applicable

Study description

Background summary

Rationale: Invasive fungal infections (IFIs) can be life threatening, especially in prolonged neutropenic patients. The overall mortality in this group has decreased from 60-80% in the past to 30-40% today because of better diagnostics and antifungals. It is essential to diagnose IFIs and start the right treatment as soon as possible to increase survival rates of the patients. Nowadays, HR-CT as imaging technique and galactomannan (GM)-test (Elisa) in blood and fluid (obtained by broncho-alveolar lavage) are together considered the *gold standard* for diagnosing IFIs, but both techniques have their limitations and provide probable diagnosis at best. It is therefore of invaluable importance to have another non-invasive test which can provide a higher sensitivity and specificity for diagnosing these IFIs. 18F-FDG-PET, and even better the combined PET-CT scan (which correlates anatomic with pathophysiologic imaging) might be this important non-invasive imaging technique with better characteristics to early diagnose IFIs.

Study objective

Objective: The primary objective of this pilot study is to compare FDG-PET-CT with HR-CT alone and to HR-CT and galactomannan test together for early diagnosing IFIs in neutropenic patients.

Study design

Study design: All twelve patients will undergo, within 48 hours of the HR-CT, an FDG-PET-CT scan (low dose CT) on the mCT (Siemens) camera at the Department of Nuclear Medicine and Molecular Imaging. The FDG-PET-CT will be evaluated qualitatively and quantitatively by calculation of the maximal Standardized Uptake Value (SUVmax). These quantitative parameters will be correlated with the results of the galactomannan-tests. Treatment schedule will be similar as normal treatment procedures, i.e. treatment regimen will not depend on the results of the FDG-PET-CT. We hope to find that FDG-PET-CT is able to localize IFI with more accuracy and give us pathognomic signs in this group of patients for having an IFI. This pilot study can form the basis for larger patient studies to see if FDG-PET-CT is able to detect IFI with greater sensitivity and specificity and eventually replace the invasive galactomannan-test by broncho-alveolar lavage.

Study burden and risks

Radiation dose considerations:
Use of positron emitting radionuclides means exposure to ionizing radiation.

Because of the potential hazard of radiation, guidelines for the exposure of healthy volunteers and patients are specified in *Besluit Stralingsbescherming (BS 2000), artikel 60, Staatsblad 2001, 397*, according to the guidelines of the International Commission on Radiological Protection.

The radiation exposure of one FDG-PET-CT (low dose CT) is approximately 9.1 mSv (7.6 mSv for FDG-PET and 1.5 mSv for low dose CT). This complies with category IIb, IRCP 62.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients (age > 18 years) with a hematologic disease who probably or possibly have an IFI. That means:

* Prolonged (or expected prolonged) neutropenia (leukocyte count < 1,0x109 or granulocyte count < 0,5x109, or leukocyte count < 1,5x109 or granulocyte count < 1,0x109 and decreasing due to chemotherapy), and
* Axillary temperature * 38, 5°C, not reacting on treatment with wide-spectrum antibacterial drugs for 72 hours, and
* A positive HR-CT scan, suspect for an IFI and
o A positive galactomannan-test in serum or fluid acquired by BAL, or positive in both materials (N<=6)
o A negative galactomannan-test GM in both serum and BAL fluid (N<=6)

Exclusion criteria

* Patients with age < 18 years
* Female patients who are pregnant
* Patients with claustrophobia or other reasons that make the scanning impossible, such as unable to lie still, need of oxygen, and so on.
* Patients who are hemodynamically instable
* (Pre)terminal patients for which the investigation is too burdensome
* Patients who may clinically not be able to undergo the study
* Patients without prolonged or expected prolonged immunocompromised condition (less than 14 days)
* Patients without positive signs of IFI on HR-CT

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2011
Enrollment:	12

Type:	Actual

Ethics review

Approved WMO Date:	28-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36625.042.11