Use of combined FDG-PET/CT in diagnosing infectious complications in patients treated with intensive chemotherapy and stem cell transplant recipients for haematological malignancy.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON30325

Source
ToetsingOnline

Brief title
Diagnostic value of FDG-PET/CT in febrile neutropenia

Condition

- Other condition
- Haematopoietic neoplasms (excl leukaemias and lymphomas)
- Fungal infectious disorders

Synonym
febrile neutropenia, fever after chemotherapy

Health condition

febriele neutropenie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: FDG-PET, febrile neutropenia, mucosal barrier injury, mycosis

Outcome measures

Primary outcome

In the analysis the correlation between clinical defined infection (CDI) or

microbiologically defined infection (MDI) and abnormalities on FDG-PET will be

studied.

Secondary outcome

NA

Study description

Background summary

Fever during chemotherapeutic induced neutropenia (febrile neutropenia) is a frequent problem and is considered to be a sign of possible urgent and life threatening infectious complications of hemato-oncologic treatment until the opposite has been proven. In 30-50% of patients infection can be pointed out as the cause of fever. During persistent fever in spite of broad-spectrum antibiotic treatment antifunal therapy aimed at invasive Candida or Aspergillus infections is added.

Recent studies in our own hospital recently showed that febrile neutropenia is not a specific indicator of infection. The hypothesis is that increase in

C-reactive protein and fever initially is caused by inflammation of mucosa of the digestive tract in reaction to cytotoxic treatment of haematological malignancies. Infection subsequently results from mucosal barrier injury.

Since FDG accumulates in infectious foci, FDG-PET seems to be an promising diagnostic technique in these patients. Studies in our own hospital investigating the value of FDG-PET in solving fever of unknown origin and diagnosing metastatic infectious disease clarified that abnormalities on PET often prejudge anatomical disturbances seen on conventional radiological techniques. The presence of a combined PET/CT-scan facilitates the possibility to combine FDG-PET and the currently used thoracic high resolution CT-scanning in one session when invasive fungal infection is suspected.

Study objective

The expectation is that FDG-PET demonstrates or excludes infectious complications earlier than current practice, resulting in more efficient use of other diagnostic methods and therapy. Besides early detection and treatment of invasive fungal infections positively influences treatment outcome.

Study design

In a prospective, descriptive analysis the capability of FDG-PET to delineate a localized inflammatory process causing febrile neutropenia earlier than current daily practice is investigated. FDG-PET is therefore added to the regular diagnostic work-up.

Study burden and risks

A maximum of 2 PET-scans per person will be made, at a minimal 3 day interval. No adverse effects are to be expected. Potential relevant abnormalities on PET will be confirmed as much as possible using current diagnostic techniques.

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

- admission and treatment at the department of hematology because of a hematological malignancy
- expected duration of neutropenia >7 days;and any of the following:
* C-reactive proteïn > 50 mg/l
* febrile neutropenia > 3-4 days despite aimed empirical or aimed antibiotic therapy
* persistant bacteraemia with coagulase negative Staphylococci
* pulmonary HRCT inidicated because of suspected pulmonary Aspergillosis

Exclusion criteria

- hemodynamic instablility
- diabetus millitus in which insulin has to be administered within 4 hours of the PET-scan either bloodglucose levels exceed 15 mmol.l
- pregnancy or lactation

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL11231.091.06