Pilot study using Fluorine-18 labeled leucocytes in diagnosing infections.

Published: 20-09-2010
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The purpose of this study is to obtain an impression of the general image quality and clinical value of leucocyte PET/CT in visualizing infectious foci in the body.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34884

Source
ToetsingOnline

Brief title
Pilotstudy Leucocyte PET/CT

Condition

- Bacterial infectious disorders

Synonym
bacterial infection, fever without focus

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: uit de exploitatie van de afdeling Nucleaire Geneeskunde Isala

Intervention

Keyword: diagnosis, infection, labeled leucocytes, PET/CT

Outcome measures

Primary outcome

1.Image quality

2. Sensitivity and specificity of LeucoPET/CT in detecting infectious foci.

Secondary outcome

n.a

Study description

Background summary

Traditional leucocyte scintigraphy is a common and old procedure in detecting infectious foci. Positron Emission Tomography (PET/CT) using fluorine-18 labeled leucocytes (Leuco PET/CT) is new method, that may be able to detect infectious foci with a much greater resolution. Worldwide experience with this method is still limited.

Study objective

The purpose of this study is to obtain an impression of the general image quality and clinical value of leucocyte PET/CT in visualizing infectious foci in the body.

Study design

This is a pilot study in 40 patients with a infectious clinical problem will undergo Leuco PET/CT. This groups consists of 10 patients with a diabetic foot (query osteomyelitis), 10 patients with a staphylococcus aureus bacteremia (query location of septic emboli) and 20 patients with fever of unknown origin. Image quality will be qualitatively assessed. Sensitivity in detecting infectious foci will be calculated. As gold standard a composite reference standard will be used, obtained by combining all clinical, biochemical, bacteriological information as well as all imaging.

Study burden and risks

Patient burden
-time investment of 4-5 hours, including 2 wait periodes, consisting of a short visit for blood draw (15-30 min), a short visit for reinjection of radiolabeled leucocytes (15 min), and a longer visit to undergo the PET/CT scan (< 1 hr)
-radiation dose of approx. 8 mSv
-laying motionless in supine position for PET/CT
There are no specific risks associated with this study.

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

-AGe > 18 yrs, and
-Informed consent, and
-Satisfies definition of group 1, 2 or 3:;Group 1: Suspected osteomyelitis or septic arthritis in diabetic foot patient
Group 2: patients with staphylococcus aureus bacteremia, proven by bloodculture
Group 3: restgroup, among which fever-of-unknown-origin

Exclusion criteria

-Antibiotics use > 7 days and evident clinical response as a result
Leukopenia (affects sensitivity, too few cels for radiolabeling) < 2000 / mm3
Pregnancy
Lactation
Unable to tolerate blood collection and PET/CT

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-09-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	20-09-2010
Application type:	First submission

Review commission: METC Isala Klinieken (Zwolle)

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	NL31293.075.10