Open-label, multicenter study of the 18F labeled PET/CT (positron emission tomography / computed tomography) tracer BAY 86-9596 following a single intravenous administration of 200 or 300 MBq (corresponding to <= 18 µg mass dose), for evaluation of radiation dosimetry, plasma pharmacokinetics, safety and tolerability in healthy volunteers (200 MBq) as well as investigation of safety, tolerability and diagnostic performance in patients (300 MBq) with non small cell long cancer, breast cancer, hea

Published: 25-02-2010
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Primary objective:Explorative investigation of the tumor detection rate with BAY 86-9596 in comparison to that of 18F-fluorodeoxyglucose (FDG)Secondary objectives:- Determination of radiation dosimetry and pharmacokinetics of BAY 86-9596 in healthy…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57022

Source
ToetsingOnline

Brief title
D-FMT: PET-POM study (proof of mechanism)

Condition

- Other condition

Synonym
Cancer, malignant neoplasm

Health condition

Healthy volunteers, patients with cancer, patients with inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer Schering Pharma AG

Intervention

Keyword: Healthy volunteers, Patients with cancer, Patients with inflammations, Tracer BAY 86-9596

Outcome measures

Primary outcome

Explorative investigation of the tumor detection rate with BAY 86-9596 in

comparison to that of 18F-fluorodeoxyglucose (FDG)

Secondary outcome

- Determination of radiation dosimetry and pharmacokinetics of BAY 86-9596 in

healthy volunteers as well as orientating search for any metabolites using TLC

- Evaluation of BAY 86-9596 compared to FDG in patients with cancer and

inflammation

- Evaluation of safety and tolerability of BAY 86-9596 in patients and healthy

volunteers

Study description

Background summary

BAY 86-9596 is not registered as a medicine. BAY 86-9596 is a drug that is being developed for the diagnosis of different kind of cancers (non small lung cell lung cancer, breast cancer and head and neck cancer) using a PET-scan. In particular to differentiate between the new drug BAY 86-9596 and the current used method (FDG) for the above mentioned cancers and inflammations occurring in the body. This should lead to improvements in diagnosis for future cancer patients.

Study objective

Primary objective:
Explorative investigation of the tumor detection rate with BAY 86-9596 in comparison to that of 18F-fluorodeoxyglucose (FDG)

Secondary objectives:
- Determination of radiation dosimetry and pharmacokinetics of BAY 86-9596 in healthy volunteers as well as orientating search for any metabolites using TLC
- Evaluation of BAY 86-9596 compared to FDG in patients with cancer and inflammation
- Evaluation of safety and tolerability of bAY 86-9596 in patients and healthy volunteers

Study design

Open label, multicenter, single-dose, explorative radiation dosimetry and diagnostic study in (i) healthy volunteers and (ii) patients with cancer as well as patients with inflammation showing lesions in previously performed FDG PET/CT.

Intervention

The study will start with a screening. At the screening a physical examination

will take place and a few other standard medical assessments will be performed (ECG, vital signs). Furthermore a blood and urine sample will be taken for laboratory tests. For patients: a pregnancy test if applicable.

Study healthy volunteers: predose assessments will be done (determination body weight, physical examination, a blood and urine sample will be taken for laboratory tests, ECG, vital signs). On day 1 the subjects will receive BAY 86-9596 and 3 PET and 3 PET/CT scans will be done. On several time points blood will be taken and urine will be collected. The subjects will be asked for possible side effects on regular basis. Furthermore ECG, vital signs, blood and urine safety examinations will be done on day 1 and day 2.

Study patients: predose assessments will be done (determination body weight, physical examination, a blood and urine sample will be taken for laboratory tests, ECG, vital signs and a pregnancy test if applicable). On day 1 the subjects will receive BAY 86-9596 and 1 PET/CT acquisition will be done. The subjects will be asked for possible side effects on regular basis. Furthermore ECG, vital signs, blood and urine safety examinations will be done on day 1 and day 2.

Finally a follow-up call will be done and normally end the study. Home pregnancy test for female patients if applicable.

Study burden and risks

In this trial, BAY 86-9596 will be used in humans for the first time. Animal studies have yielded no evidence of likely side effects. Theoretically, as with any substance which does not occur naturally in the body, it is not possible to rule out completely the possibility of BAY 86-9596 having side effects, including hypersensitivity reactions and even severe allergic shock.

The radiation exposure associated with the radioactivity of the 18F-labelled BAY 86-9596 and the x-rays used in the CT scans is of the same magnitude as that associated with PET/CT studies performed routinely in hospitals. The radiation-related risks are low, however, and medically justifiable.

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

Healthy male or female volunteers between 50 and 65 years of age
Male or female cancer patients between 30 and 80 years of age
Male or female patients with inflammation between 35 and 75 years of age

Exclusion criteria

Healthy volunteers: clinical significant abnormalities at medical examinations
Patienten: concurrent severe and/or uncontrolled and/or unstable medical disease other than cancer or inflammation which could compromise participation in the study

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2010
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N.A.
Generic name:	D-FMT

Ethics review

Approved WMO Date:	25-02-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-05-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-05-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-12-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-04-2011

Application type:	Amendment
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
EudraCT	EUCTR2009-013098-16-NL
CCMO	NL31315.042.10