Positron Emission Tomography for detection of histologic transformation of indolent non-Hodgkin’s lymphoma: a pilot study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23241

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Non Hodgkin Lymphoma; Positron Emission Tomography

Sponsors and support

Primary sponsor: VU Medical Center Amsterdam, department of Hematology.
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

- Maximal Standard Uptake Value (SUVmax), SUV mean and intraindividual variability

Secondary outcome

N/A

Study description

Background summary

A pilot study to investigate which PET tracer, FDG or FLT, is best suited for early PET diagnosis of transformation in patients with low grade NHL. Study design: a prospective observational study. Patient population: patients with newly diagnosed follicular lymphoma and patients with newly diagnosed histological transformation of follicular lymphoma.

Study objective

The survival of patients with histological transformation might be better as treatment is started when there is still limited disease. PET-scanning can be used to to diagnose the process of transformation early. But it is not clear yet, which tracer, FLT or FDG, is better in distinguishing indolent lymphoma from histological transformation.

Study design

- At entry

- After performing both PET-scans

Intervention

Patients will receive two PET-scans: one with FDG tracer and one with FLT tracer.

After the diagnosis and before performing both PET-scans, patients have not received any treatment. PET-scans will be performed minimally one day, maximally 7 days apart, in random order.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with newly diagnosed follicular lymphoma or newly diagnosed histological transformation of follicular lymphoma proven by histological examination.

2. Ann Arbor stage at diagnosis: II, III or IV.

3. At least one lesion > 2 cm diameter.

4. After the diagnosis and before performing both PET scans they have not received any treatment.

5. Ability to remain supine for 60 min. (PET)

6. Written informed consent.

Exclusion criteria

1. Uncontrolled diabetes mellitus.

2. Physical inability to access PET facilities.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2008
Enrollment:	34
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-10-2008
Application type:	First submission

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
NTR-new	NL1426
NTR-old	NTR1487
Other	METC VUmc : 2008/191
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A