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

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The aim of this pilot study is to investigate which PET tracer (FDG or FLT) is best suited for early PET diagnosis of transformation in patients with low grade NHL

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Lymphomas non-Hodgkin's B-cell |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON32557

**Source**
ToetsingOnline

**Brief title**
PET scan and histologic transformation of indolent NHL

### Condition

- Lymphomas non-Hodgkin's B-cell

**Synonym**
follicular lymphoma, low grade lymphoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** histologic transformation, indolent non-Hodgkin's lymphoma, PET

## Outcome measures

### Primary outcome

1. detection rate (number of true positive PET lesions for either tracer, using

CT as reference test)

2. relative tracer uptake (SUV) for either tracer (lesion by lesion analysis,

lesion with highest uptake of FDG or FLT)

3. lowest and highest SUV for either tracer within one patient.

### Secondary outcome

not applicable.

# Study description

### Background summary

The survival of patients with histological transformation might be better as treatment is started when there is still limited disease (2), creating a need for a non-invasive technique to diagnose the process of transformation early. PET scanning can be this technique, but it is not clear yet, which PET tracer; FDG or FLT, can distinguish better between indolent and transformed lymphoma. The tracer that distinguishes best could then be used in a follow-up study to analyze whether increasing uptake of the tracer in the same patient indicates histologic transformation.

### Study objective

The aim of this pilot study is 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

The design of the study is a pilot study with patients with newly diagnosed

follicular lymphoma or histologic transformation. In each patient a PET scan will be made with both FDG and FLT as a tracer. It is a prospective observational study using head-to-head comparison of FLT and FDG in consecutive eligible patients with follicular and transformed lymphoma. Considering the small series in literature we expect that after including 17 patients in each group (follicular/transformed) we can determine which PET tracer is best in distinguishing indolent from transformed lymphoma.

**Study burden and risks**

PET-CT: 1,2+3,5+3,5=8,2 mSv for both scans including CT. PET scans will be performed minimally 1 day, maximally 7 days apart, in random order.

## 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

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

Exclusion criteria
1. Uncontrolled diabetes mellitus.
2. Physical inability to access PET facilities.

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 27-11-2008 |
| Enrollment: | 34 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 24-09-2008 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# 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 | NL24544.029.08 |