

# Evaluation of the fractional uptake rate (FUR) in 18F-FDG PET/CT to assess tumour metabolic activity

Published: 14-03-2023

Last updated: 30-01-2025

Primary objective: To investigate whether FDG PET quantification using the FUR is superior compared to the clinically used SUV. Secondary objectives: 1) To evaluate whether the metabolic tumor activity Km can be accurately assessed with 18F-FDG PET...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Miscellaneous and site unspecified neoplasms malignant and unspecified
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON53508

### Source

ToetsingOnline

### Brief title

FUR evaluation in oncologic PET

### Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

### Synonym

Lung cancer, lymphoma

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** 18F-FDG, Metabolic activity, Oncology, Positron emission tomography

## Outcome measures

### Primary outcome

Level of correlation between the FUR and Km and assess whether this is superior compared to the correlation between the SUV and Km.

### Secondary outcome

Accuracy of the FUR to assess the glucose consumption of tumors.

Inter-subject variation in time-integrated arterial 18F-FDG concentration.

## Study description

### Background summary

As most tumours have a high glucose consumption, important information on tumour metabolism can be obtained from PET imaging using 18F-FDG as a radioactive glucose analogue. From literature it is known that quantitative analysis improves the clinical value of 18F-FDG PET. However, instead of measuring the true tumour glucose consumption Km, in current clinical practice the 18F-FDG uptake is measured at a certain time after administration as a surrogate for Km, the so-called standardized uptake value (SUV). As the SUV suffers from a number of important shortcomings, discrepancies between Km and the SUV have been reported which may lead to erroneous conclusions regarding disease progression based on the SUV.

Alternatively, pharmacokinetic modelling approaches facilitate accurate Km assessment. Unfortunately, these approaches typically require complex mathematical modelling, lengthy dynamic PET imaging and/or invasive arterial blood sampling and are therefore not compatible to current clinical oncologic 18F-FDG PET scanning. However, from these models it can be derived that at late time points after administration Km can be approximated using a simplified approach known as the fractional uptake rate (FUR). Our hypothesis is that PET quantification based on the FUR is feasible in clinical routine and will result in superior 18F-FDG PET quantification compared to the SUV.

## Study objective

Primary objective: To investigate whether FDG PET quantification using the FUR is superior compared to the clinically used SUV.

Secondary objectives:

- 1) To evaluate whether the metabolic tumor activity  $K_m$  can be accurately assessed with  $^{18}F$ -FDG PET using the FUR.
- 2) To investigate the impact of the use of patient-specific versus a (scaled) population-based input function on the accuracy of  $K_m$  assessment using the FUR.

## Study design

This study is a cross-sectional observational study in lung cancer and/or lymphoma patients that will receive an  $^{18}F$ -FDG PET/CT scan as part of standard clinical care. In contrast to the clinical protocol in which patients will receive a static whole-body PET/CT scan following a waiting time of 50-60 minutes after  $^{18}F$ -FDG administration,  $^{18}F$ -FDG administration will be performed inside the PET/CT scanner after which a dynamic whole-body PET/CT scanning protocol will be conducted. After the dynamic PET scan, the standard static whole-body PET/CT scan will be performed for the standard clinical diagnosis. Consequently, patient examination is not prolonged, nor is patient diagnostics altered in any way.

## Study burden and risks

During the study three additional blood samples will be taken. Blood sampling itself can cause bruises. Infections or continued bleeding on the other hand are very rare. The additional effective dose resulting from the extra low-dose CT examination is between 1-10 mSv (risk category IIb, ICRP 62 publication), which is recommended and acceptable for research conducted with oncologic patients having an intermediate to moderate level of societal benefit. All PET/CT examinations are performed using a CE-registered clinical PET/CT system (Discovery MI 5R, GE Healthcare). Furthermore all examinations conform the intended purpose of the system. The maximum 50 minute dynamic whole-body PET/CT examination which is additional to the standard care PET/CT examination performed 60 minutes after  $^{18}F$ -FDG administration comprises the same examination as in an earlier study which has been approved of by the Medical Ethics Committee (see also NL74609.068.20)

## Contacts

### Public

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Oncologic patients who receive an 18F-FDG PET/CT scan for their standard care.  
Be competent and be 18 years or older

### Exclusion criteria

Diabetes

Not fasted > 4 hours

Physical exercise within 24 hours

Earlier treatment for carcinoma with radio/chemo-therapy

Active inflammation (fever > 38 degrees, CRP > 5)

Any condition or medical indication (such as claustrophobia) that indicates that the patient will not be able to lie still for the duration of the dynamic PET/CT examination.

Pregnant or breast feeding

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-01-2024

Enrollment: 30

Type: Actual

## Ethics review

Approved WMO

Date: 14-03-2023

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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

ClinicalTrials.gov

CCMO

### ID

NCT05654675

NL82359.068.22