

# Integrated 18F-FDG PET/CT in the staging of patients with suspected primary ovarian cancer.

Published: 19-03-2007

Last updated: 14-05-2024

The aim of the study is to prospectively evaluate the accuracy of integrated whole body positron emission tomography/computed tomography (PET/CT) in staging patients with primary ovarian cancer, with use of histological findings as the reference...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Ovarian and fallopian tube disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON29961

### Source

ToetsingOnline

### Brief title

integrated PET/CT for primary ovarian cancer

### Condition

- Ovarian and fallopian tube disorders

### Synonym

ovarian cancer, ovarian neoplasm

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Ziekenhuis Maastricht

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

## Intervention

**Keyword:** integrated PET/CT, ovarian cancer, staging

## Outcome measures

### Primary outcome

The primary outcome measure is the difference in ovarian carcinoma stage according to the International Federation of Gynecology and Obstetrics (FIGO), based on PET/CT and surgery/histological findings.

### Secondary outcome

niet van toepassing

## Study description

### Background summary

Combined PET/CT has been shown to be superior to other imaging modalities in most tumor types. However current data on the use of combined PET/CT for staging primary ovarian cancer is limited. If combined PET/CT turns out to be a reliable modality for assessing the extent of disease in patients with primary ovarian cancer, tumor and metastases can be better localised and excised and the amount of unnecessary surgical interventions (such as lymphadenectomy) and its complications can be reduced.

### Study objective

The aim of the study is to prospectively evaluate the accuracy of integrated whole body positron emission tomography/computed tomography (PET/CT) in staging patients with primary ovarian cancer, with use of histological findings as the reference standard.

### Study design

observational pilot study

### Study burden and risks

niet van toepassing

## Contacts

### **Public**

Academisch Ziekenhuis Maastricht

p debeyelaan 25  
6229 HX Maastricht  
Nederland

### **Scientific**

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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 years and suspicion of primary ovarian cancer based on the results of complaints, physical examination and findings from ultrasound

### Exclusion criteria

pregnancy, unwillingness to give informed medical consent, evidence of significant psychiatric disorder by history or exam, previous pelvic-abdominal surgery, radiotherapy

within six months of study entry or chemotherapy.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-06-2006

Enrollment: 20

Type: Anticipated

### Medical products/devices used

Registration: No

## Ethics review

Approved WMO

Date: 19-03-2007

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	ID
CCMO	NL12219.068.06