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

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ovarian and fallopian tube disorders
Study type	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

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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