Sentinel node in ovarian cancer

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Primary Objective: - Determine whether or not a sentinel node procedure in patients with ovarian cancer is feasible.Secondary Objective(s): - The anatomical location(s) of the sentinel node(s).- Incidence of false negative nodes.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON37538

Source
ToetsingOnline

Brief title
SONAR study

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
malignancy of the ovary, ovarian cancer

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: Cancer, Node, Ovarian, Sentinel

Outcome measures

Primary outcome

Percentage of patients in whom sentinel node(s) will be identified.

Secondary outcome

- Location of the sentinel node(s)

- Incidence of false negative nodes.

Study description

Background summary

As most cancers, ovarian cancer also spreads to regional lymph nodes. The sentinel lymph node is hypothetical the first lymph node or group of nodes draining a cancer. If the sentinel node(s) does not contain cancer, there is a high likelihood that the cancer has not spread to other lymph nodes. This means that, at least theoretically, a radical lymphadenectomy or extensive lymph node sampling could be omitted and thus the associated morbidity. The sentinel node technique was proven to be effective in other cancers such as breast cancer and malignant melanoma, and in the gynaecological field in vulvar cancer. Currently sentinel node studies are done for cervix en uterine cancer.

Study objective

Primary Objective:
- Determine whether or not a sentinel node procedure in patients with ovarian cancer is feasible.

Secondary Objective(s):
- The anatomical location(s) of the sentinel node(s).
- Incidence of false negative nodes.

Study design

Phase I: feasibility study to detect sentinel nodes: mapping the lymphatic drainage of the ovaries.

Study burden and risks

The surgery is prolonged with 20-25 minutes due to the required incubation time after injection of the blue dye and radioactive isotope. A scintigram will be performed the day after the surgery to determine whether residual radioactive lymph nodes can be detected. The scintigram will only be performed if the patient is capable to be transported to the nuclear department. No extra blood samples will be taken, no extra visits, physical examinations or other tests are necessary. There is a 0.9% risk of an allergic reaction to the blue dye of which 0.07% severe (anaphylactic shock). The dose of radioactive isotope given does not give adverse side effects, either to the patients or the personnel present in the operating theatre.

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

The following patients will be included:
Cohort 1: patients with a high suspicion of an ovarian malignancy in whom a median laparotomy and a frozen section analysis is planned.
Cohort 2: patients with endometrial cancer in whom a staging laparotomy is planned.

Exclusion criteria

- Previous surgery of the ovaries.
- Previous vascular surgery of the aorta, caval vein, and/or iliac vessels
- Previous lymphadenectomy of lymph node sampling in the iliac or para-aortal region.
- History of a malignant lymphoma
- History of a malignant tumour in the abdominal cavity.
- Previous allergic reaction to blue dye.
- Pregnant or lactating patients

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):	10-10-2012
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	05-09-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-07-2013
Application type:	Amendment
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	NL40323.068.12