Sentinel node in ovarian cancer.

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1) To determine whether or not a SN procedure in patients with OC is feasible through injection of the tracers in the ovarian ligaments, when the ovarian tumour has already been resected.2) To determine if blue colorization of the sentinel nodes is...

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

Summary

ID

NL-OMON42766

Source
ToetsingOnline

Brief title
SONAR-2

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
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: ovarian cancer, sentinel node

Outcome measures

Primary outcome

Percentage of patients in whom it is feasible to identify sentinel nodes in

case the malignant ovarian mass has already been resected.

Secondary outcome

- To determine if blue colorization of the sentinel nodes is related to the

time-interval between injection and retroperitoneal exploration?

- To determine if the technique becomes more accurate by using a mobile

gamma-camera and / or multimodality radioactive and fluorescence guidance

during the surgical procedure.

Study description

Background summary

As most cancers, ovarian cancer also spreads to regional lymph nodes. The concept of sentinel lymph node surgery is to see whether the cancer has spread to the very first lymph node or sentinel node (SN). If the SN does not contain cancer, then there is a high likelihood that the cancer has not spread to other lymph nodes. This means that, at least theoretically, a radical lymphadenectomy could be omitted and thus the associated morbidity. The SN technique has been proven to be effective in other cancers such as breast cancer and malignant melanoma. In the gynaecological field it has been shown to be effective in vulvar cancer. Recently we have shown that the SN procedure performed through the injection of tracers into the ovarian ligaments is feasible and promising in patients with clinical early stage ovarian cancer (OC). Injection of radioactive tracers resulted in the identification of SNs in all 21 patients. Before a multicentre randomized controlled trial can be initiated, still some questions have to be answered.

Study objective

1) To determine whether or not a SN procedure in patients with OC is feasible through injection of the tracers in the ovarian ligaments, when the ovarian

tumour has already been resected.
2) To determine if blue colorization of the sentinel nodes is related to the time-interval between injection and retroperitoneal exploration?
3) To determine if the technique becomes more accurate by using a mobile gamma-camera and / or multimodality radioactive and fluorescence guidance during the surgical procedure.

Study design

phase I feasibility study.

Intervention

During surgery tracers are injected in the ovarian ligaments to identify sentinel node(s).

Study burden and risks

In case the tracer is injected with the adnexal mass still in situ, the surgery is prolonged at maximum with 20-25 minutes due to the required incubation time after injection of the blue dye and radioactive isotope. A scintigram will be performed 24 hours 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 no risk of tumour dissemination by injecting the tracers in the ovarian ligaments. There is a 0,07 to 2,7% risk of an allergic reaction to the blue dye. 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

- Patients with a high suspicion of a malignant ovarian tumour planned for exploratory laparotomy with frozen section, staging procedure in case of malignancy.
- Patients in whom the ovarian malignant tumour has already been resected and a second surgical procedure is planned to complete the staging procedure including lymph nodes.

Exclusion criteria

- Age <18
- Age > 85 years.
- Mentally incompetent to give informed consent.
- 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.
- An allergy for human albumin.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	26-10-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-10-2016
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
ClinicalTrials.gov	NCT02540551
CCMO	NL53246.068.15