Laparoscopic cytoreduction After Neoadjuvant ChEmotherapy

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The primary objective of this study is to examine whether MIS is non-inferior to laparotomy in terms of disease free survival (DFS) in women with advanced stage EOC that received 3 to 4 cycles of NACT.

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

Summary

ID

NL-OMON52155

Source
ToetsingOnline

Brief title
LANCE

Condition

- Reproductive neoplasms female malignant and unspecified
- Obstetric and gynaecological therapeutic procedures

Synonym
Cancer of the ovaries, Epithelial ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Er is geen vergoeding voor deze studie-Kosten worden gedragen door de afdeling

Intervention

Keyword: laparosopic surgery, neoadjuvant chemotherapy, Ovarian cancer, surgical cytoreduction

Outcome measures

Primary outcome

Disease free survival

Secondary outcome

Health related quality of life

Optimal cytoreduction

Complete cytoreduction

Overall survival

Surgery related morbidity and mortality

Intraoperative complications and injuries

Conversion rate to laparotomy

Study description

Background summary

Women with advanced stage epithelial ovarian cancer are treated with a combination of chemotherapy (Carboplatin and Paclitaxel) and an operation with the aim to remove all visible tumor. With this surgery at least the uterus, ovaries and omentum are removed. But depending on the extent of the disease the surgery may also include removal of part of the bowel, the spleen, the peritoneum covering the abdominal wall and diaphragm, etc. . The standard approach for this type of surgery is a median laparotomy with an incision from the symphysis up to, in some cases, the xiphoid.

For the treatment sometimes it is decided to start with this surgery, a so called primary debulking. An alternative approach is to start with neoadjuvant chemotherapy with the aim to reduce the tumor load which will lead to a more limited dissection. This research will focus on this last group.

For women treated with neoadjuvant chemotherapy tumor response will be evaluated with a CT scan after two or three cycles of chemotherapy. At debulking surgery all identified tumor deposits will be removed. The advantage of a laparotomy is that it gives good access to the abdominal cavity with good visibility and the ability to feel for tumor deposits. A laparotomy is therefore still considered standard of care.

However, there is considerable experience with the use of laparoscopic surgery in gynaecologic oncology. For endometrial cancer the laparoscopic approach is standard of care. For early stage ovarian cancer laparoscopic surgery is also the preferred approach. The advantage of laparoscopy is faster recovery with less blood loss en reduced pain.

Study objective

The primary objective of this study is to examine whether MIS is non-inferior to laparotomy in terms of disease free survival (DFS) in women with advanced stage EOC that received 3 to 4 cycles of NACT.

Study design

The study is an international, prospective, randomized, multicenter, non-inferiority phase III trial

Intervention

Laparoscopic cytoreductive surgery

Study burden and risks

Both laparoscopic and open surgery are used in gynaecologic oncologic surgery. Women often recover quicker after a laparoscopic procedure. The risk of this study is that small tumordeposits are missed that would have been identified with a open procedure which may possibly lead to a worse oncologic outcome. We expect this risk to be small as the inclusion criteria are very restrictive and only allow participation of women who have shown to have a very good repsonse aftre neoadjuvant chemotherapy.

The follow up is comparable with the standard of care with the exeption of two additional visits after 3,5 and 4,5 years.

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

Women with ovarian cancer who have shown good respons after three or four courses of neoadjuvant chemotherapy. The ca 125 is normalised and on CT scan no disease in anatomical locations that would make a laparoscopic complete debulking not possible. They should be fit for either laparoscopic or open surgery. In addition women with a good respons but with a ca 125 that is not normalised can be included after a laparoscopic evaluation at the start of surgery.

Exclusion criteria

Intraabdominal disease that would preclude a complete debulking. Not fit for laparoscopic surgery or laparotomy.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2023
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-06-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NCT04575935
CCMO	NL77252.018.21