Laparoscopy to predict the result of primary cytoreductive surgery in advanced ovarian cancer patients.

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To investigate whether laparoscopy is cost-effective in predicting which patients will benefit from primary surgery and which patients should be treated with neoadjuvant chemotherapy and interval surgery instead.

Ethical review	-
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON34677

Source
ToetsingOnline

Brief title
LAPOVCA

Condition

- Reproductive neoplasms male malignant and unspecified
- Ovarian and fallopian tube disorders

Synonym
ovarian cancer, ovarian neoplasmata

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZONMW

Intervention

Keyword: cytoreductive surgery, laparoscopy, ovarian neoplasma, predictive value of tests

Outcome measures

Primary outcome

Our main outcome will be the frequency of futile laparotomies e.g. suboptimal primary debulking procedures.

Secondary outcome

Secondary outcome measures will be the frequency of complete cytoreductive surgery (no residual tumor), residual tumor <1 cm, progression free survival, overall survival, morbidity, quality of life, days in hospital, and costs.

Study description

Background summary

Traditionally standard treatment of patients with advanced ovarian cancer is complete cytoreductive surgery, defined as debulking surgery without residual tumor, followed by chemotherapy. In cases of suboptimal debulking at primary surgery patients will be treated with neoadjuvant chemotherapy and interval debulking to gain an optimal survival. In these patients primary surgery is futile, causing reduction of quality of life, increasing costs and chances of more complications, without survival advantage.
In The Netherlands about 40% of primary debulking surgery is suboptimal. Diagnostic laparoscopy added to the standard clinical and CT evaluation in selecting patients eligible for primary debulking surgery is likely to be more reliable in prediction of suboptimal surgery. Randomised research on reduction in morbidity and costs while adding diagnostic laparoscopy to conventional staging has not yet been performed.
Hypothesis: Adding laparoscopy to conventional staging in patients suspected of advanced ovarian carcinoma could prevent unnecessary laparotomy, thus limiting morbidity and costs.

Study objective

To investigate whether laparoscopy is cost-effective in predicting which

patients will benefit from primary surgery and which patients should be treated with neoadjuvant chemotherapy and interval surgery instead.

Study design

A multicentre prospective randomized clinical trial. After inclusion and informed consent 200 patients will be randomized to additional laparoscopy or direct primary cytoreductive surgery.

Intervention

Additional staging laparoscopy as compared to the standard conventional staging in the selection for primary cytoreductive surgery or neoadjuvant chemotherapy plus interval cytoreductive surgery.

Study burden and risks

Women randomised for additional staging laparoscopy will have an extra operation under general anesthesia and will be admitted for one day in the hospital. Diagnostic laparoscopy is a routinly performed technique for gynaecologists, with a low rate of complications. The open technique is thought to be the safest in our groep of patients. With the laparoscopy a futile primary debulking can be prevented. All patients have to fill in three questionaires.
If laparoscopy proves to be cost-effective in improving the frequency of optimal debulking with equal or better survival rate, this procedure will be added to conventional staging in all patients. Therefore future patients will benefit from this trial.

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

All patients suspected of having advanced ovarian cancer between 18-80 years of age, who are scheduled to undergo primary debulking surgery, who signed informed consent

Exclusion criteria

Contraindications for primary cytoreductive surgery, and therefore, exclusion criteria for this study will be:
1. Poor general conditions (WHO performance status >3) and age > 80 years or under 18 years.
2. Intrahepatic metastatic disease > 1 cm.
3. Extra-abdominal metastatic disease (excl. inguinal lymph nodes or pleural fluid).
4. Imaging suggestive of
a. Peri-aortic lymphadenopathy larger than 1 cm above the level of the renal veins.
b.Extensive peritoneal carcinomatosis > 1 cm at the diaphragmatic level.
c. Extensive bowel mesentery involvement
5. Large immobile pelvic tumor, probably requiring bowel resection for complete debulking
6. Contra-indication for laparoscopic surgery

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2011
Enrollment:	200
Type:	Actual

Ethics review

Not available

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	NL31441.018.10