A randomized controlled multicenter phase III trial comparing cytoreductive surgery followed by intravenous chemotherapy versus intravenous chemotherapy alone for recurrent platinum-sensitive ovarian cancer

Published: 26-01-2012
Last updated: 13-01-2025

There is still no level I-II evidence for cytoreductive surgery in recurrent ovarian cancer. This is also the conclusion of a Cochrane Review of Galaal et al. published in June 2010. The most active chemotherapy in platinum sensitive recurrent...

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

Summary

ID

NL-OMON35952

Source
ToetsingOnline

Brief title
Surgery for Ovarian Cancer Recurrence (SOCceR)

Condition

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

Synonym
cancer of the ovaries, ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Een aanvraag voor KWF subsidie voor datamanagement is ingediend

Intervention

Keyword: cancer, ovarian, recurrent, surgery

Outcome measures

Primary outcome

Comparing progression free survival (defined as the interval between date of randomization and progressive disease or death of any cause) in the two study-arms

Secondary outcome

Comparing overall survival (defined as the interval between date of randomization and date of death), quality of life, morbidity, mortality, toxicity and tumour response following treatment in the two arms.
With respect to secondary cytoreductive surgery : determining the effect of complete and incomplete surgery on progression free survival and overall survival, identifying predictive factors and criteria for patient selection for complete surgery.

Study description

Background summary

Each year approximately 1100 women are diagnosed with ovarian cancer and around

900 will die of the disease. This high mortality rate is due to the fact that at least 60% of the patients presents with an advanced stage disease. In the Netherlands, the population-based 5-year survival rate of these patients is only 20-25%. Standard front-line therapy for advanced stage ovarian carcinoma is primary cytoreductive surgery followed by intravenous platinum and taxane-based chemotherapy. Patients with first recurrence of ovarian cancer are treated with palliative chemotherapy according to the national guideline. The median overall survival reported in large prospective chemotherapy only trials is 18 and 29 months. The progression free survival in the superior arms in these chemotherapy only trials is 8, 6 and 13 months. Where the role of cytoreductive surgery is widely accepted in the initial treatment of ovarian cancer, its value in recurrent ovarian cancer has not yet been established. Many studies, nearly all retrospective and with selected patient cohorts have demonstrated a clear survival benefit for patients undergoing secondary cytoreductive surgery. In 2008, Bristow et al. conducted a meta-analysis on 2019 patients with secondary cytoreductive surgery for recurrent ovarian cancer. Median overall survival ranged from 10-62 months. Progression free survival was not reported.

Study objective

There is still no level I-II evidence for cytoreductive surgery in recurrent ovarian cancer. This is also the conclusion of a Cochrane Review of Galaal et al. published in June 2010. The most active chemotherapy in platinum sensitive recurrent ovarian cancer provided only a limited activity with a median overall survival of 29 months. Improvement is clearly needed for these patients. Survival rates up to 62 months in patients with complete tumor resection are reported in series with selected patient cohorts. Therefore a randomized controlled trial comparing surgery and chemotherapy versus chemotherapy alone is needed.

Study design

Multicenter, randomized controlled Phase III trial

Intervention

Control arm: intravenous platinum containing chemotherapy

Experimental arm: secondary cytoreductive surgery followed by intravenous platinum containing chemotherapy

Study burden and risks

Studies suggest that secondary cytoreductive surgery can be accomplished with a similar morbidity and mortality rate as primary debukling for advanced ovarian

cancer. Significant per-operative morbidity is estimated 19,2% and consist of postoperative hemorrhage, intra operative bowel injury and intra-abdominal infection. The peri-operative mortality rate is estimated 1,2%. We expect that a maximum of 5% of patients in the experimental group will start chemotherapy more than six weeks after secondary cytoredutive surgery because of surgery related morbidity.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-Zuid 10
6525 GA Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-Zuid 10
6525 GA Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >= 18 years
• First recurrence of histologically or cytologically proven epithelial ovarian cancer, primary peritoneal cancer or fallopian tube cancer of FIGO stage Ic-IV (FIGO system 1988)
• First-line treatment consisted of complete or optimal (<= 1 cm) cytoreductive

surgery and a minimum of six courses (neo-adjuvant) platinum-taxol based chemotherapy
• A clinically disease-free interval of at least 6 months after end of first-line treatment, the latter defined as the day the last chemotherapy was administered
• First recurrence defined as clinical and radiological signs (CT-scan) of recurrence or elevated CA 125 (GCIG criteria) and radiological signs (CT-scan)
• If there is any doubt whether or not an abnormal finding on CT-scan is recurrent ovarian cancer, confirmation of recurrence with cytological or histological investigation is warranted
• Good performance status (ECOG 0-1)
• Ascites < 500 ml (pocket < 8 cm on ultrasound examination)
• Complete resection seems possible (estimated by a gynecologic oncologist)
• Adequate hematological, renal, and hepatic function to permit platinum based chemotherapy: WBC > 3.0 x 10*/L, platelets > 100 x 10*/L, serum creatinine < 1.25 x upper normal range (40-90 µmol/L), serum bilirubin < 1.25 x upper normal
range (< 17 µmol/L)
• Informed consent must be obtained and documented according to national and local regulatory requirements and the local rules followed in the institution before randomization
• Quality of life baseline questionnaires should be filled in after informed consent, preferably before randomization but at least before start treatment

Exclusion criteria

• Participation in interfering trial
• Non-epithelial or borderline ovarian tumours
• Other primary malignancy except for carcinoma in situ and basal or squamous cell carcinoma of the skin
• Patients with platinum-refractory or resistant tumours
• Intra-abdominal metastatic disease that hampers complete cytoreduction
• Extra-abdominal metastatic disease that hampers complete cytoreduction
• Palliative surgery already planned (e.g. bowel surgery)
• Patients with secondary, third and later recurrence
• Any disease, medical history or medication not allowing surgery and/or platinum based chemotherapy
• Prior therapy with respect to recurrence

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:	Recruitment stopped
Start date (anticipated):	16-07-2012
Enrollment:	230
Type:	Actual

Ethics review

Approved WMO Date:	26-01-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-04-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-07-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-08-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-08-2012
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-05-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20627
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL36413.091.11
OMON	NL-OMON20627