Improving quality of care for patients with recurrent ovarian cancer

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

Summary

ID

NL-OMON45807

Source
ToetsingOnline

Brief title
MOGYN21 QoC Ovarium Carcinoma

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cancer of the ovary, Ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: PharmaMar (farmaceut)

Intervention

Keyword: Ovarian cancer, Patient reported outcome, Quality of care, Quality of life

Outcome measures

Primary outcome

the velocity of disease symptom relief and its duration by systemic therapy

measured by questionnaires on PROs and response to therapy. Primary endpoints:

changes in outcomes on QoL and symptoms due to disease and treatment.

Secondary outcome

Petient reported disease symptoms top 3, response to therapy as measured by

CA-125 and radiology, distress, emotional wellbeing, Empowerment and change in

patient reported needs.

Study description

Background summary

ovarian cancer is a major cause of cancer related death among women. The disease is usually advanced at diagnosis, because specialist referral is delayed due to vague nature of presenting symptoms. Primary treatment is successful, but most patients experience recurrence. Complaints due to disease and therapy overlap. Furthermore treatment schedules are similar in response rate and survival rates. Toxicity of therapy as scored by the physician is best documented, but varies depending on type of chemotherapy. Moreover most knowledge is acquired in clinical trials and not in daily practice. Patient reported outcome (PROs) concerning effects on symptoms, velocity of relief and quality of life (QoL) by the different regimens is sparce. Also it is unknown which symptoms are best relieved. Most trials take into account progression or survival as primary endpoint but not often symptom relief, which is especially important for patients with recurrent disease, without no chance of cure anymore. Knowledge on rating of problems and needs of patients with recurrent ovarian cancer (ROC) to support them in the course of their disease is needed to come to an evidence based and patient centered treatment of choice together with the patient. Physicians most frequently use the Common Toxicity Criteria (CTC) scale for grading of side effects of treatment, but discrepancies with

patient experiences is high. Routine collection of PROs may therefore improve patient expectations and management. In this project we intend to augment knowledge by PROs of different chemotherapy schedules for recurrent ovarian cancer in order to improve shared decision making with the physician.

Study objective

primary objective of this project is to explore the relief of symptoms due to ROC, the speed with which this occurs by different chemotherapy schedules and development of complaints due to the regimen of chemotherapy. Secondary we intend (1) to assess preferential symptom relief by patients, (2) to correlate toxicity and symptoms of disease to tumor assessed response to chemotherapy and (3) to correlate symptom relief by psychosocial context.

Study design

prospective exploratory study

Study burden and risks

participation in this study imposes no additional risks to patients, except the completion of questionnaires (<24months, 10 times one questionnaire that takes 20 minutes of the patients' time)

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 recurrent EOC or tubal carcinoma or peritoneal carcinoma;
• Histologically and/or cytologically proven epithelial ovarian cancer (including carcinosarcoma of the ovaries)
• Measurable or evaluable disease confirmed by radiological imaging OR ca 125
• ECOG <=2
• Estimated life expectancy >=12 weeks
• Patients must be accessible for treatment and follow-up
• Fit to receive chemotherapy

Exclusion criteria

• Patients with benign ovarian cancer;
• Patients with non-epithelial cancer;
• Bowel obstruction, sub-occlusive disease or presence of symptomatic brain metastases;
• Patients with other malignancy occurring within 5 years before enrollment
• Patients with impaired cognitive functioning or analphabetic patients
• Patients with an inability to fill in surveys digitally

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO Date:	09-05-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-09-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-01-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-01-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-03-2017
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

No registrations found.

In other registers

Register	ID
CCMO	NL57147.091.16