LOROCSON study: Late Onset Recurrent Ovarian Cancer: Surgery Or Not.

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The median progression-free survival in the chemotherapy- alone arm is assumed to be 13 months. It is assumed that the addition of surgery increases the median progression-free survival with four months.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27781

Bron
NTR

Verkorte titel
LOROCSON

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Progression-free survival.

Toelichting onderzoek

Achtergrond van het onderzoek

A randomized phase III study for the treatment of recurrent epithelial ovarian cancer: chemotherapy alone versus chemotherapy followed by secondary cytoreductive surgery in

patients with a disease-free interval of more than 6 months: LOROCSON Late Onset Recurrent Ovarian Cancer: Surgery Or Not
Objectives:
The general purpose of the study is to evaluate the benefits and risks of secondary cytoreductive surgery in patients with late onset recurrent epithelial ovarian cancer. The study will be prospective, multi-center, Study endpoints are primary: progression-free survival and secondary: survival, toxicity, surgical treatment related complications and quality of life.
Patient selection criteria:
* Inclusion: recurrence of epithelial ovarian cancer, after first line chemotherapy with a disease-free interval of at least 6 months, age> 18 years, WHO Performance status 0-2. The first-line therapy should have consisted of at least 4 courses of either cisplatin or carboplatin.
* Exclusion: more than one line chemotherapy, complete bowel obstruction, metastasized carcinoma (other tumor), leptomeningeal or brain metastases.
Randomization:
* Stage at initial diagnosis (early I-IIa vs. advanced stage IIb-IV).
* Length of disease free interval between the time of curation and registration to this protocol (between 6 months and 2 years versus more than 2 years).
* Response to 2nd line induction chemotherapy, i.e. first three cycles of this trial (no change versus partial remission versus complete remission).
* Number of measurable tumor lesions at registration (1 versus more than 1).
* Largest tumor size of recurrence at registration (< 5 cm vs. > 5cm).
* Institution.
* Peritonitis or ascites present at initial surgery.
* Tumor-diameter after initial surgery (no, 0-1 cm, >1 cm).
Trial design:
After registration the patient will immediately start the first course of chemotherapy. After the induction chemotherapy the response to therapy will be evaluated. In case of progressive disease the patient will go off treatment. The other patients will be randomized to either continuation of the chemotherapy without surgery (treatment A) versus secondary cytoreductive surgery followed by chemotherapy (treatment B).
Clinical evaluation, laboratory tests and follow up:
During the course of the study the following examinations will be done: history and general physical examination, gynecological examination and ultrasound, WHO performance status, laboratory analysis (serum CA 125, Hb, Ht and albumine) abdominal-pelvic computed tomography (CAT scan) and the QLQ OV 28.
Patient registration
The following items will be registered: institution and responsible physician, initials of the patient, birthday and hospital record number, date of last chemotherapy cycle (and type of chemotherapy), date of diagnosis of recurrence, stage of disease at initial diagnosis (FIGO), number of measurable lesions and largest diameter, WHO performance status, peritonitis or ascites present at initial surgery and tumor-diameter after initial surgery (no, 0-1 cm, >1 cm)
Statistical considerations
With a power analysis we calculated that 522 patients must be randomized in a period of 5 years. Assuming that 75% of the patients will reach the randomization procedure 700 patients should be registered. This means that 140 patients should be registered each year.

Doel van het onderzoek

The median progression-free survival in the chemotherapy- alone arm is assumed to be 13 months. It is assumed that the addition of surgery increases the median progression-free survival with four months.

Onderzoeksproduct en/of interventie

After registration the patient will immediately start the first course of chemotherapy. After the induction chemotherapy the response to therapy will be evaluated. In case of progressive disease the patient will go off treatment. The other patients will be randomized to either continuation of the chemotherapy without surgery (treatment A) versus secondary cytoreductive surgery followed by chemotherapy (treatment B).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Recurrence of epithelial ovarian cancer, after first line chemotherapy with a disease-free interval of at least 6 months, age> 18 years, WHO Performance status 0-2. The first-line therapy should have consisted of at least 4 courses of either cisplatin or carboplatin.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

More than one line chemotherapy, complete bowel obstruction, metastasized carcinoma (other tumor), leptomeningeal or brain metastases.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2005
Aantal proefpersonen:	700
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-10-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL306
NTR-old	NTR344
Ander register	: MEC 2005-128
ISRCTN	ISRCTN50678517

Resultaten

Samenvatting resultaten
N/A